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Dietary Practices and Disease Management Practices in Diabetes' Patients with Good and Poor Glycemic Control at Kenyatta National Hospital (KNH)

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CERTIFICATION AND DECLARATION

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ABSTRACT

Background: Compliance to appropriate dietary recommendation and observation of appropriate disease management practices is a well-known integral part in the care and management of Type-2-diabetes. Dietary and lifestyle practices of T2DM subjects in Kenya are still unclear.

Objective: This study aimed at assessing T2DM risks profile, dietary practices and exploring the experiences of patients attending the outpatient diabetes clinic at the Kenyatta National Hospital (KNH), Nairobi, Kenya

Study Design: A case-control study design was conducted with cases referring to the study subjects with T2DM whose blood glucose levels that are outside the above ranges suggested by NICE and controls referring to study subjects whose blood glucose levels lie in the ranges suggested by the NICE guidelines.

Methods: Associations were studied in 157 T2DM outpatients aged 18 years and above (up to 65years), undergoing treatment and care at the KNH outpatient diabetes clinic. Dietary intake was assessed using a 24-hour recall questionnaire. Disease management practices such as medication use, medical check-ups amongst others was obtained from an interviewer-administered questionnaire.

Data Analysis: Data was analyzed using SPSS v.22.0 for Windows

Results*:* One-hundred and fifty seven participants (75 males, 82 females). 54.7% of the study population had attained the NICE recommended target post-prandial blood glucose level range (under 8.5mmol/L). Abdominal obesity, BMI and dietary practices were risk factors that were analyzed for this population.

Conclusion: The risk factors for type 2 diabetes mellitus associated with poor glycemic control described in this urban population included low self-reported compliance to recommendations given by health-service providers. The poor glycemic group of study subjects also had a statistically significant higher number of hospital admissions due to diabetic ketoacidosis. Reasons for non-compliance and non-adherence to recommendations by patients should be addressed by future studies to provide more insight in this area.

Key words: Type-2-diabetes mellitus, KNH, diabetes risk factors, dietary intake assessment, disease management practices.

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ACRONYMS AND ABBREVIATIONS

ACCORD	Action to Control Cardiovascular Risk in Diabetes Study Group
BMI	Body Mass Index
DMH	Diabetes History
FAO	Food and Agriculture Organisation
HbA_{1c}	Glycated haemoglobin
IDF	International Diabetes Federation
KNH	Kenyatta National Hospital
KSh.	Kenya Shillings
MDG(s)	Millenium Development Goal(s)
MDRTC	Michigan Diabetes Research and Training Center
NCD(s)	Non-Communicable Disease(s)
NICE	National Institute for Health and Clinical Excellence
NSE	Nairobi Stock Exchange
QALy	Quality Adjusted Life Years
SIGN	Scottish Intercollegiate Guidelines Network
SPSS v.22.0	Statistical Package for the Social Science version 22.0
SSA	Sub-Saharan Africa
T1DM	Type 1 Diabetes Mellitus
T2DM	Type 2 Diabetes Mellitus
UM	University of Michigan
WDF	World Diabetes Foundation
WHO	World Health Organisation
WHR	Waist-to-Hip Ratio

1.0 CHAPTER ONE: INTRODUCTION

This chapter gives an overview of Type 2 diabetes in general and prevention and management practices. It encompasses the background information, the rationale for the study, the study objectives, and the source reference.

1.1 Background Information

Type 2 diabetes mellitus is a metabolic disorder of multiple etiology (WHO, 2014). The disorder is characterised by chronic hyperglycemia accompanied by problems in the metabolic processes of carbohydrates, protein and fat in the human body. T2DM is related to defects in insulin secretion and/or insulin action. Clinical diagnosis of diabetes is usually evidenced by the manifestation of symptoms such as polyuria, polydipsia, and unexplained weight loss. Its presence is confirmed by the clinical measurement of hyperglycemia. The World Health Organization (WHO) has provided guidelines that can be used to assess the range of blood glucose considered as indicative of diabetes mellitus: venous plasma glucose ≥11.1 mmol/l at two hours after a 75 g oral glucose load (oral glucose tolerance test (OGTT)); or fasting venous plasma glucose (FPG) ≥7.0 mmol/l; or glycated haemoglobin A1c (HbA_{1C} ≥ 6.5 % or 48 mmol/mol) (**Table 1**).

Table 1: Diagnostic Tests and Glucose Cut-off Values

Diagnostic test	Normal	Pre-diabetes	Diabetes
Haemoglobin A1c	<5.7%	5.7 – 6.4%	≥6.5%
Fasting plasma glucose	<100mg/dL	100 - 125mg/dL	≥126mg/dL
Randomn plasma glucose	<130mg/dL	130 - 199mg/dL	≥200mg/dL
Oral glucose tolerance test	<140mg/dL	140 – 199mg/dL	≥200mg/dL
For A1c and fasting glucose, the diagnosis must be confirmed by a second test			
A random glucose ≥200mg/dL must be confirmed with fasting glucose ≥126mg/dL or the OGTT			

Source: WHO Guidelines, 2008

As has been the case worldwide, diabetes and other non-communicable diseases are now a threat to the Kenyan national development (IDF, 2008). Non-communicable diseases are often associated with complications like obesity, dyslipidemia and hypertension (Gray et al., 1998). They result in long-term complications such as coronary heart diseases and renal problems that

can be fatal if not well managed and are usually very costly to treat. In Kenya, diabetes prevalence is estimated to be 3.3% (WHO), and the WHO predicts a rise to 4.5% by 2025 (Mcferran L., 2008). This figure is calculated based on regional projections and is believed to exclude a significant population that may be potential patients with diabetes. It is further re-enforced by the fact that over 60% of diabetes cases diagnosed in Kenya are usually detected at the health care facility by patients seeking services of unrelated complaints. Therefore, a large proportion of diabetic cases in the country often go undetected (IDF 2007).

The current disease burden depicts the urgent need for allocation of more resources towards prevention and health promotion. It is necessary that primary health care takes greater responsibility for chronic diseases. The WHO recommendations are currently of concern to the Kenyan government (WHO- Health Report 2012). The financial demands for curative care reduce funding available for implementing effective health-care policies (Kenya Draft Health Financing Strategy, 2012). The WHO has suggested the implementation of changes in the financing and delivery of services models for chronic conditions both within Kenya and other sub-Saharan African countries in general. It is necessary to re-evaluate health care funding so as to ensure an appropriate allocation and sufficient proportions are set aside for non-communicable diseases (NCDs) especially diabetes. Reduction of poverty, increase in treatment compliance, improvements in diabetic control and reduction of complications and co-morbidities are factors that can be achieved by lowering the financial burden on individuals. An increase in public funding thus is key so as to decrease further the burden placed on health care services.

Health promotion strategies facilitate individual assessment for risk of diabetes and identification of common symptoms, hence encouraging access to health services (Maina W. et. al., 2011). Educating individuals whose families have a history of diabetes in several generations could help reduce modifiable risk factors (Chege M., 2010) and be used for screening. Diabetes should be actively managed and monitored by regular clinic attendance. Patients need to be assisted, where practical. They have a big responsibility to play in monitoring of their blood glucose trends. This improves the chance of achieving optimal glycemic control (Chege M, 2010; NICE, 2011). Nutrition education is a process that aimed at the general improvement in a patient's ability to cope with their disease. It also increases the

ability to make informed decisions concerning disease management and medication. It motivates patients' behavior and lifestyle modification. This stimulates the discontinuation of undesirable dietary and lifestyle habits.

Diet modification and consistency in appropriate meal patterns have been said to help control blood glucose (Wolever et. al., 1999). Nutrition education aimed at the prevention and management of diabetes is crucial in reduction of the disease burden (NICE, 2011). Prevention and management training should mainly focus on high risk groups, for example, those with diabetic family history, obesity, reduced physical activity and glycemic impairment among others. Increased knowledge changes attitudes towards diabetes and enables in its prevention as it acts as a motivator for individuals to take responsibility for their health. For instance, the United Kingdom 'change4life' strategy was aimed at the promotion of healthier behaviour and practices (National Health Service, 2013). A similar model could be adopted in Kenya successfully as has been seen in the United Kingdom.

Dietary management is the basic foundation of glycemic control in diabetes mellitus patients. Patient education, that is, nutrition counselling and disease management advice is now seen as a necessary component in the control of diabetes. It should this be included as a component in all diabetes management programs and aim at reaching all patients with diabetes. Education facilitates the improvement of dietary behavior, changes in physical activity, broadening of nutritional knowledge and improvement of clinical outcomes manifested as lower blood glucose and HbA_{1C} levels and lipid concentrations (Funnell M. et. al., 2011; Deakin T.A. et. al, 2006).

However, some diabetes patients fail to consider the dedication and effort they must give to achieve optimal glycemic control. The adoption of new and healthy food habits is not an easily achieved goal for diabetes patients regardless of their social-economic status and education level. There are several studied barriers to dietary adherence. They include complications with daily life (eating out, social events) and temptations, need for food planning, need for constant self-care, denial of the severity of the disease, poor understanding of diet-disease associations, misinformation, lack of appropriate social support and time constraints with regards to food preparation (Travis, 2007). Regimen adherence problems tend to be common in persons with

diabetes, thus making glycemic control difficult to attain. (Alan, 2006). Non-adherence to recommended dietary protocols is of particular interest and significance in the diabetic population as it reduces the chances of attaining recommended glucose levels.

1.2 Rationale for the Study

Addressing the issue of diabetes and other non-communicable diseases, in general, is no longer something that Kenya can leave to the future. A significant proportion of the current disease burden in the country is already attributed to NCDs (Kenya Nutrition Bulletin, 2013). NCDs are predicted to increase further as the country's main focus is on the control of infectious diseases and reduction in the high rates of mortality and morbidity accompanying childbearing and infancy. There is an urgency to put in place comparable efforts to address the phenomenon of non-communicable diseases. Diabetes and other related non-communicable diseases are not predictable consequences of contemporary life. Prevention is achievable with reasonable modifications in lifestyles that are entirely matched with life as it is in the 21st century. However, the necessary adjustments in smoking and alcohol habits, physical activity, and dietary practices may not be easy. They demand sustenance and encouragement through investments in education, changes in food policies, and even changes in urban infrastructure. Though the necessary behavioral changes are the same everywhere, the ways to realize them will differ countrywide. Different approaches to be used correspond to cultural, social, and economic features.

Kenya is lacking in population-based data on the disease burden and trends of diabetes. No comprehensive research that can be used to inform policy on the best practices for the control and management of diabetes is in existence. Therefore, slight attention is directed to the prevention and control of non-communicable diseases. Much of the emphasis, during medical training and in human and financial resources allocation is focused on infectious diseases.

In spite of the varied risk factors of the disease across the country as well as the limited data on the dietary behavior of T2DM in Kenya, the study offers an evaluation of the dietary practice and disease management practices of T2DM patients attending the KNH diabetes outpatient clinic. The justification of this study has its basis on the fact that it will attempt to review the regular food intake of Type 2 diabetes patients attending the clinic to assess their

current dietary practice. It will also seek to establish challenges faced in following this advice to attain a "good" glycemic control. It will determine some of the reasons some diabetes patients fail to attain the recommended target glycemic level despite all patients targeted being sourced from the same clinic. It is intended to bring positive changes in the diets of Type-2-diabetes patients thereby contributing to reduced diabetes complications.

The study is further intended to provide public health educators with the desired information that will empower them towards planning and provision of an effective and efficient diabetes education. Also, the findings of this study are intended to reignite the awareness of the Kenyan government on the burden of diabetes that faces Kenyan families as well as the country at large.

1.3 Objectives

Several studies in Kenya have focused on the assessment of the pre-disposing risk factors of type-2-diabetes for individuals in different set-ups. These studies have however not realized the extent to which diabetes patients are central in diabetes care as they decide through their dietary adherence and lifestyle (disease management practices) how to cope with the disease.

1.3.1 General Objective

To establish the disease management practices and dietary practices in T2DM patients attending the diabetes outpatient clinic at Kenyatta National Hospital.

1.3.2 Specific Objectives

- To evaluate the dietary compliance of T2DM patients and assess its association with T2DM risks profile
- To explore the experiences of T2DM patients who attend the diabetes outpatient clinic at Kenyatta National Hospital.
-To determine disease management related reasons for patients with diabetes not attaining the recommended blood sugar levels.

2.0 CHAPTER TWO: LITERATURE REVIEW

This chapter describes literature on the epidemiology, health care system in Kenya, the role of nutrition, the role of nutrition counselling, and, the role of exercise in the management of T2DM. This section also provides evidence from other studies that will enable comparable and informed judgment on our study findings.

2.1 Risk Factors

The main predisposing (modifiable) risk factors for diabetes are obesity, unhealthy diets, and physical inactivity. Interventions are required to transform all unhealthy lifestyles. These changes will mostly take place due to the implementation of an organized variety of interventions to encourage individuals realize and maintain healthy weight; to consume from healthy dietary regimes; and, to participate in daily physical activity.

Obesity is the excessive accumulation of body fats and is clinically assessed using BMI. The most commonly used measure of obesity is a BMI of ≥30 kg/m2 or anthropometric measures like waist circumference and waist-to-hip ratios (WHR) (Sharma et. al., 2005). Until recently, obesity has not been much of a concern in SSA due to the yet to be resolved under-nutrition, low levels of urbanization and mechanization, which in the past has enabled the people from this region to live a physically active life. Obesity has been implicated as an important risk factor for developing T2DM with some studies having reported strong correlations between T2DM and obesity (James, 1998). Sharma et al.(2005) distinguish the abdominal obesity from the subcutaneous type with regards to the risk of T2DM. In the particular study, findings revealed the abdominal type of obesity to be a more important risk factor in comparison to subcutaneous obesity.

Obesity has been associated with a significant negative effect on morbidity and mortality, and weight management is an integral part of diabetes care. Weight loss in obese individuals usually results in a great reduction in mortality, blood pressure, lipid profiles, arthritis-related disability and other complications. People with T2DM can receive instruction on dietary choices for realizing weight loss. Such coaching will go hand-in-hand with significant improvement in glycemic control. Education message options include simple caloric

restriction, reduction in fat intake levels, utilization of low rather than high glycemic index carbohydrates, and restriction in the total amount of dietary carbohydrate. The SIGN guideline on the management of obesity gives elaborate information on the recommendations on prevention and management of obesity within the clinical setting, in children, adolescents, and adults. The SIGN guideline encompasses: diagnosis of overweight and obesity; primary prevention of obesity; dietary treatment of obesity; lifestyle and behavioral interventions; medications and bariatric surgery; maintenance of weight; and, subsequent prevention of weight regain after treatment. Additionally, the guideline explains the benefits of weight loss on glycemic control in people with established diabetes and the prevention and remission of both established diabetes and impaired glucose tolerance. It includes a summary of weight loss interventions in people with diabetes. The SIGN obesity guideline is a vital primary resource for evidence-based recommendations on management of obesity (SIGN Management of Obesity, 2010).

The increased occurrence of T2DM has also been attributed to the nutrition transition from the healthy traditional diet to a Western type of diet; that is high in refined carbohydrates, saturated fats, cholesterol and low in fiber (Misra, 2008). The traditional African diet is high in complex carbohydrates, pulses and vegetables. It tends to reduce obesity risks as it is characterized by low sugar and saturated fat content. Cereals form an important part of the African diet. Maize is one of the staple food in Kenya and can be consumed in the grain form or ground into a powder that is used to make ugali. Whole grain consumption in the diet reduces the risk of development of metabolic syndrome, as well as sustain the maintenance of a healthy weight. Naturally, whole-grain foods are low in fat. The soluble fiber in whole grains helps maintain blood sugar levels and prolongs digestion of minerals. Widespread consumption of fresh leafy vegetables and traditional herbs or plants which is characteristic of a traditional African diet offers a high total phenol content and antioxidant activity. Africa has an abundance of various varieties of fruits. Flavonoids found in fruits and vegetables are protective against heart diseases and its associated risk factors. The problem in this region is that consumption of fruits and vegetables is all time low from infancy and throughout adulthood indicating an under-utilization of the potential health benefits of fruits and vegetables in this region.

The traditional diet composition exposes one to a low risk for diabetes and other chronic diseases. However, the observed upsurge in prevalence of diabetes in Kenya and other African countries, suggests that there is probably a gradual departure (nutrition transition) especially in the urban centers, from the usual traditional diets to a westernized diet and lifestyles. The transition in turn elevates diabetic risks as well as other related risk factors. Popkin (2006) recorded changes in the diets of the populations. These include increased intake of edible oils, animal foods, caloric sweeteners and low intake of fiber. These changes were related to the global increases in the food supply with a massive decrease in prices of these commodities.

Challenges in the assessment of nutrition and lifestyle factors in Africa are mainly due to some limitations in the classification of food groups, imprecision in data collection as well as varied cultural views (Joost, 2008). In spite of these limitations, studies based on food habits should be encouraged and performed in all areas within the sub-Saharan Africa region.

Other lifestyles changes that have been implicated as possible risk factors for T2DM include alcohol consumption and cigarette smoking. The effect of these lifestyles on the risk of T2DM is not well studied in the region.

Un-modifiable risk factors for diabetes include age, family history, and ethnicity. In 2010, the peak age for the onset of diabetes was estimated to be 40-59 years of age, and by 2030, the highest prevalence of T2DM is expected to be observed in the oldest age group 60-79 years (Thyssen et. al., 2011). A positive family history was observed to be more frequent in diabetic patients in Sudan and thus was observed as an independent risk factor. Other studies in South Africa found the proportion of African (Black) subjects with known T2DM that ranges from 28-33% in contrast to the proportion of Europeans in that country (McLarty et. al., 1990). These findings suggest that in addition to other factors, ethnicity may contribute to an increase in the prevalence of T2DM.

2.2 Epidemiology

Diabetes and other non-communicable diseases have a higher prevalence in high-income countries. The majority of the disease burden from diabetes, approximated at 80% of people with diabetes live in low- and middle-income countries (IDF Diabetes Atlas). The high prevalence in the developing regions is attributable to their larger populations. The developing world faces a dilemma of the double burden of disease making their situation more delicate.

Kenya has an estimated prevalence rate of diabetes at 3.3%. The value is calculated based on regional projections and is likely to be an underestimation of the real value. In Kenya, most of the population seek medical care when they have serious complaints. Furthermore, 60% of diabetes' diagnosis in Kenya is from patients that go to the health care facility with seemingly unrelated complaints. Therefore, a large proportion (about two-thirds) of people with diabetes are unaware that they live with the disease (IDF 2007).

Several modifiable risk factors come to the fore as driving forces of the rising prevalence of type 2 diabetes in Kenya. These factors associated with urbanization include: consumption of refined carbohydrates; consumption of high-fat diets; lack of physical activity due to sedentary lifestyles; lack of exercise or circumstantial reduction of physical exercises occasioned by the availability of motorized transport; watching television; and, playing computer games for long hours. These common urban events and lifestyles are now reaching rural Kenya.

2.3 The Health Care System in Kenya

Kenya's health facilities are distributed regionally. Community dispensaries and health centres provide the most basic level of service. Level-5 (district level) hospitals, provincial general hospitals and the referral centers, such as the Kenyatta National Hospital (KNH), provide more specialist services (Wamai, R., 2009). Widespread disparities in health care service provision may be attributed to socio-economic, gender and geographical differences. Studies have shown that approximately only 77% of Kenyans who are ill utilize the available health care (Turin D., 2010). Uneven health service provider distribution exists. A huge number are deployed in cities and metropolitan hospitals in comparison to the rural areas (Kenya Draft Health Financing Strategy, 2012). Hospitals often operate with the co-existence of public and private (amenity)

wards in one setting, managed by the same staff (Turin D., 2010). Conditions in the public levels are inferior compared to the expensive private wards (Turin D., 2010). In Kenya, as in many sub-Saharan African countries, the health system is focused on the treatment of acute rather than chronic conditions (Diabetes Leadership Forum, 2010). A well-developed primary health-care system which necessary to tackle chronic diseases such as diabetes is not in place (Mcferran L., 2008). The health-care system in Kenya is affected by various significant factors, in which the double burden of both communicable and non-communicable diseases is key. The system requires restructuring to align itself with the developing challenge of the double burden of disease. Prevention; management, care and treatment; and research are all activities that are manifested by the existence of a strong and functional health care environment.

2.4 Glycemic Management: The Role of Nutrition

HbA_{1C} is a commonly accepted measurement of long-term glycemic control. It is indicative of the average plasma glucose levels over the previous two to three months in a single measure. The HbA_{1C} test can be carried out on a patient at any time of the day as it eliminates the necessity of any special preparations such as fasting. It is thus a key measure for assessing glycemic control in people with established diabetes. In 2006, WHO considered HbA_{1C} as a candidate tool for the diagnosis of diabetes mellitus and monitoring of glycemic control. Despite being a 'gold standard,' HbA_{1C} measurement is not widely available in many countries throughout the world, and there are aspects of its measurement that are problematic.

Current recommendations are that HbA_{1C} be checked at least every six (6) months if the patient is well monitored ($HbA_{1C} \leq 7\%$) and on a steady oral hypoglycemic regimen, otherwise every three (3) months. Lower HbA_{1C} targets are not recommended. Generally, a target HbA_{1C} of 7.0% (53mmol/mol) in people with type 2 diabetes is adequate to decrease the risk of micro-vascular disease and macro-vascular diseases (Docstoc, 2014). Setting a target of 6.5% (48 mmol/mol) may be appropriate at diagnosis (**Table 1**). Different targets should be set for different individuals while weighing and keeping a balance between benefits and harms, especially regarding hypoglycemia and weight gain. The University of Michigan Diabetes Team suggests that health care providers should weigh patient-specific factors when considering glycemic goals as shown in the table below. Considering that it takes years for symptomatic benefits to manifest, a variety of factors may alter target levels. These include

reduced life expectancy (dependent on significant comorbidity), complications and co-morbidities associated with advanced diabetes, a history of hypoglycemic ignorance, or challenges in the ability to carry out a treatment regimen (**Table 2**).

Table 2: Targeting and Monitoring Glycemic Controlling Patients with Diabetes

<table>
<tr><td colspan="2">Target A1c should be defined based on personal assessment of risks and benefits of treatment. Below are factors marked "*" or "**" where;

"*" = factors that limit the benefit of tight control

"**"= factors that heighten the risk of tight control.

Patients lacking any of these factors should generally have an A_{1C} of <=7%.

Patients having these factors should have a goal of minimizing symptoms of hyperglycemia and to control glucose as well as possible without incurring side-effects or excessive treatment burden; while an appropriate A1c is difficult to define exactly, treatment should be aimed to keep the A1c under 9%

HbA_{1C} should be measured every 3-6 months.

If HbA_{1C} is above goal:

1. Assess treatment regimen
2. Diabetes dietary counselling or referral
3. Start or increase medication
4. Recheck HbA_{1C} in 3 months</td></tr>
<tr><td>"*": Factors limiting benefit of tight control

1. Comorbidities (e.g., end-stage cancer, severe heart failure).

2. Advanced diabetes complications (e.g., proliferative retinopathy, renal failure).

3. Inability to safely carry out treatment regimen.

4. Limited life expectancy</td><td>"**": Factors heightening risk of tight control

1. History of severe hypoglycemia (inability to treat without assistance).

2. Hypoglycemia unawareness.

3. Advanced cardiovascular or cerebrovascular disease.

4. Autonomic neuropathy (especially cardiac).

5. Comorbidities that impair the detection of hypoglycemia (e.g., alteration in mental status, alcoholism, etc.).

6. Poor social support</td></tr>
</table>

Source: UM (The University of Chicago Medical Center, 2015)

Despite its high value, the HbA_{1C} test is not widely available in Kenya due to its high cost. The HbA_{1C} test is one of the recommended tests in the Kenyan national clinical guidelines. However, most hospitals have no HbA_{1C} guidelines in place. Moreover, it is not accessible in most rural health facilities. The above reasons make the required testing of 2 to 4 times a year

almost impossible for most patients with diabetes in Kenya. Hence, there is a necessity to evaluate patients' knowledge and frequency of its use. In this case, the test commonly used to record out-patient diabetes blood sugar levels will be adopted and compared to the WHO guidelines during data analysis (**Table 1**).
The University of Michigan (UMHS Management of Type 2 Diabetes Mellitus, September 2012) recommendations for glycemic control in patients with T2DM show the importance of comprehensive and individualized nutritional counselling (**Table 2**).

In T2DM patients, diet and physical activity are essential first line therapies. Appropriate dietary choices are necessary to ensure and maintain good health. Healthy nutritional practices and lifestyles are nurtured best in childhood and adolescence. These developmental stages are important periods in the human's life where the human body is still undergoing development and is being built up to maintain a healthy adulthood later on. Many chronic diseases including diabetes do not have a sudden onset and neither cause sudden death. NCDs rather cause progressive illness and debilitation. On the contrary, poor nutritional habits established during childhood and adolescence periods are responsible for the onset and development of chronic diseases such as obesity, heart disease, osteoporosis and others. Furthermore, the Western-type diet that has been established the last decades is the main risk factor for increased morbidity and mortality. (Steyn N. et. al., 2004; Swift C. & Boucher J., 2006; and; Willett W. et. al., 2002).

It is acceptable that upholding healthy nutrition is the basis for the treatment of T2DM. It positively contributes to the maintenance of blood glucose at normal levels and reduces the complications of the disease. Recent literature advocates for the Mediterranean Diet as the most comprehensive diet choice. The Mediterranean diet is characterized by olive oil as the main source of fat. It features a high to moderate consumption foods such as fruits, herbs, cereals, fish, and legumes in combination with a lesser portion of meat and wine (Willett W., 2006; Schröder H., 2007).

According to literature, in most cases, hyperglycemia, results from poor regulation blood sugar levels. It is often the major cause of hospitalisation. Hyperglycemic patients are typically unaware of disease existence and thus follow unhealthy nutritional lifestyles that lack in an

adequate amount of physical exercise in their daily activities. On the other hand, a healthy nutritional program combined with physical exercise effectively regulates blood glucose. According to conducted research, the risk of diabetes in patients with impaired glucose tolerance reduces after a combined program of nutrition and exercise. Patients with diabetes mellitus need access to information on the positive benefits of appropriate nutritional habits, which is the major factor in regulation of blood glucose (Franz M., 2004).

It is important for the design of a nutritional program should be individual-based, relative to the dietary preferences, sex, age, work, weight, and the personal targets for different patients. Appropriate nutrition promotes the quality of life; decreases the need and incidence of hospitalisation and also the high cost of the treatment. Intensive and repeated counselling by health care providers is an issue of utmost importance. Issues of non-compliance arise because the discipline of most patients in the given instructions reduces over time. Counselling, reinforcement and routine follow-up on patients to embrace appropriate dietary habits to prevent and treat type 2 diabetes mellitus becomes a primary prevention modality (Kruger D., 2008; Brunton S., 2009).

The dietary guidelines for diabetics are more or less the same as those recommended for the general population, and they are based on the sound principles of nutrition. In the treatment of diabetes, the traditional concept of simple versus complex carbohydrates is often misconstrued by diabetics. It is rather easy to understand that choosing a healthy diet with right mixture of low and high glycemic index foods (i.e. blood glucose of a food when compared to the level realised after ingesting an equivalent amount of glucose) as well as regular exercise is a good strategy to maintain plasma glucose control. Diabetics should have an individualized nutrition therapy considering the usual eating habits as well as other lifestyle factors to ensure a successful outcome.

2.5 Abdominal Obesity

Positive associations between obesity and risks associated with T2DM have been observed, both in cross-sectional studies (Shaten et al., 1993) and in prospective studies (Cassano et al., 1992; Colditz et al., 1990). The consistency of the association across populations while

accounting for differences in measures of fatness and diagnostic criteria for diabetes in adults reflects the strength of this relationship. The risk of T2DM in adults increases continuously with increasing obesity and decreases with weight loss. An analysis of the relationship between obesity and adult-onset diabetes confirms that abdominal obesity is an important risk factor, even after controlling for smoking, family history, and, age. Since waist circumference correlates more closely with abdominal adipose tissue than BMI, the association between indicators of such obesity (e.g. waist circumference) has been studied extensively in the last two decades. Qiao & Nyamdorj (2010b) in their study conclude that, with respect to T2DM, all anthropometric measures (BMI, waist circumference, waist–height ratio, and waist–hip ratio) perform equally in predicting risk. However, data from most of the cross-sectional studies suggested that waist circumference or waist–hip ratio are better indicators compared to BMI of the risk of diabetes. The number of prospective studies was limited, and the studies covered only a few ethnic or population clusters; thus, the evidence from studies that waist circumference or waist–hip ratio is preferable is neither convincing nor generalizable. The cross-sectional studies show only possible association, and the strength of evidence may be considered as possible. All the findings from these studies provide proof that either BMI or waist circumference predicted an association with diabetes, and an elevated risk of the disease, independent of other factors. Key methodological issues that affected the ability to draw clear conclusions were emphasized by Qiao & Nyamdorj (2010b). In the studies and reviews considered, most studies used the "sensitivity and specificity" approach to determine the optimal cut-off points for anthropometric measures predicting type 2 diabetes risk. The selection of cut-off points using such an approach is arbitrary because values are based on analysis of the trade-offs between sensitivity and specificity. Though a high sensitivity is usually preferred for waist circumference measurements in health promotion (to increase rates of public awareness of obesity and diabetes), a strong specificity in diagnostic criteria is expected in clinical practice ((WHO Expert Consultation, 2008).

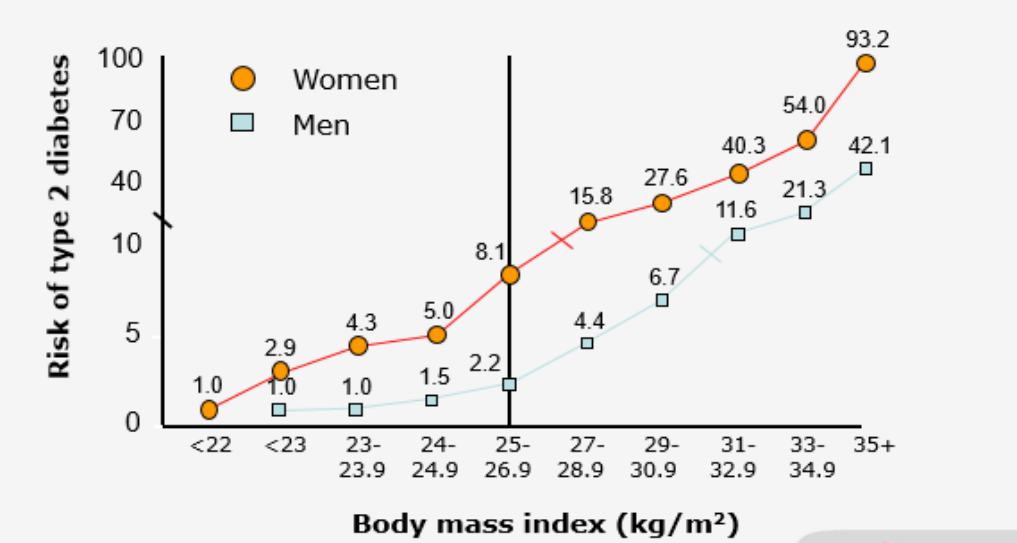

Figure 1: The relationship between BMI and the risk of developing type 2 diabetes
Adapted from Klein S and Romijn J, in Williams Textbook of Endocrinology, 10th ed, 2003
From the IDF publication: 'Diabetes and Obesity', p.25

The above-discussed measures point out some of the basic primary prevention and management interventions of diabetes. If lifestyle modifications are not adequate, the diseases set in demanding the use of the available variety of medical interventions. Many of this medical interventions, however, tend to be expensive. The essential treatment for T1DM is insulin injections for the maintenance of normal blood glucose levels. For T2DM, the treatment includes various aspects, such as observing good dietary practices, physical activity and oral or injectable glucose-lowering agents and/or insulin. Maintaining normal blood glucose levels in patients with diabetes is crucial to delay and prevent complications and co-morbidities. In comprehensive diabetes care, proper management of levels of blood pressure, lipids, and weight abnormalities is essential. Other components that can be exploited as effective prevention and control interventions in the case of diabetes and its subsequent complications include health education, early screening and detection followed by prophylaxis and treatment for diabetes co-morbidities.

Complications associated with diabetes are challenging and usually expensive to treat. Therefore, maintenance of adequate glycemic control is the most cost-effective alternative. The toll the disease takes on individuals, families, societies and economies particularly in the developing, and less developed world cannot be overstated. For many patients in Kenya,

maintenance treatment for diabetes is expensive and poses an economic challenge to most families. Consequently, some of the patients fail to adhere to treatment which exposes them to a higher risk of developing end-organ damage. Those in need of more advanced, more expensive care for diabetes-related co-morbidities are often the same people without the financial means to afford such care. The Kenya household economic survey approximates that about 46% of the Kenyan population lives on less than a dollar a day. When burdened with debilitating or life-threatening health-related issues demanding expensive advanced care, most of them are forced to sell their insufficient assets to pay for treatment. This leads to impoverishment at the individual, family and society level. Furthermore, diabetes also leads to early deaths. Most of the people affected by diabetes are aged between 40 and 59 years of age (IDF Diabetes Atlas).

Effective prevention strategies for diabetes are not necessarily costly and may bring down costs related to other related NCDs. On the contrary, both in health and economic terms, neglecting chronic diseases such as diabetes is very expensive. The costs of treatment and loss of productivity weaken and stunt economic development and negatively affect the realisation of the Millennium Development Goals (MDGs) (WDF, 2007), Vision 2030 and other national development targets. If Kenya can successfully strengthen its health systems to improve the coverage of interventions that reduce infectious disease and maternal and childhood conditions, it equally can build further capacity to address the increasing burden of diabetes and other non-communicable diseases.

A National Diabetes Comprehensive Care program in partnership with Ministry of Public Health and Sanitation and funded by World Diabetes Foundation is currently running in Kenya. The project aims to train professional health care providers country-wide on prevention and control of diabetes and establish comprehensive diabetes clinics. The development of National Diabetes Policy Documents was launched in 2010. As of June 2013, the Division of Nutrition was in the process of finalizing national guidelines for Healthy Diets and Lifestyle (Kenya Nutrition Bulletin, June 2013). The guidelines will provide clear recommendations on consumption levels and frameworks for monitoring at an individual level, promote healthy

food choices and lifestyles and support prevention of micronutrient deficiencies and diet-related NCDs.

3.0 CHAPTER THREE: METHODOLOGY

This chapter examines the qualitative and quantitative methods to be used to obtain data as per the study objectives. It also describes the study design, study site, description of the study population as well as the data collection methods and instruments to be applied in this study.

3.1 Study Area

KNH is at Kenya's apex of the referral system in the Health Sector in Kenya. It was built to fulfill the role of being a National Referral and Teaching Hospital, as well as to provide a medical research environment. The KNH complex houses among others the College of Health Sciences (University of Nairobi); the Kenya Medical Training College; Kenya Medical Research Institute and National Laboratory Service (Ministry of Health).The hospital boasts 22out-patient clinics. The study was conducted at the KNH Hospital Diabetes Outpatient Clinic (Clinic 17). Clinic 17 is under the Department of Medicine. A senior nurse officer is in charge of the unit with several staff members that they supervise such as nurses and a nutritional educator.

Patients from all over Kenya with varied diagnosis seek medical care from KNH. Sampling from this hospital will ensure a fair representation of the population. The diabetes clinic was set up 26 years ago in the Kenyatta National Hospital. The clinic runs various a range activities to support the weekly diabetes services provided to patients attending it. Some of the aims of the clinic includes the provision of education; empowerment; improved care; and, affordable and accessible care to its clients. The clinic has been identified by the Kenya Ministry of Health as a model for the management of diabetes and other non-communicable diseases (Diabetes Voice, 2006).

3.2 Study Population

The study included participants aged 18 years and above up to 70 years. The subjects were sampled from the outpatient Diabetes Clinics of Kenyatta National Hospital (KNH).

Inclusion Criteria:

Participation in the study was open to all T2DM patients who visited the diabetes outpatient clinic in during the period of data collection. The written consent from was read out orally to

the patients and all T2DM patients who gave consent were included in the study. The control group comprises patients with T2DM visiting the same clinic at the same period but have a poor glycemic control (**Table 3**). Case definition of cases and controls has been defined in the study design. Purposive sampling was used to sample patients after briefing by the health care provider. Purposive sampling is done when the researcher selects the study subjects because of a certain characteristic. The sampling method was adopted since the researcher selected the study subjects and assigned them to either the case or control group based on their blood glucose levels. This was done so as to avoid interfering with the patient-doctor relationship and also to increase the confidence of the subjects in taking part in the study. Participants included could communicate either in English or Swahili language.

The health service providers were aware of the study being conducted and thus data was collected as the patients waited to see the health service providers or after they had been assessed. This was possible since patients had to pass through one of the laboratories to have their measurements of blood glucose and weight taken before coming to the clinic. The data collector created rapport with the patient, informed them of the purpose of the study being conducted and notified them that participation in the research was voluntary. The researcher provided a certificate of consent to the patients willing to sign while ensuring confidentiality of the information provided. After this, the questionnaire was administered by the researcher.

Exclusion Criteria:

Subjects with gestational diabetes were excluded from the study. This is because their energy, and nutrient needs are likely to be higher to compensate for pregnancy. T1DM patients were excluded to ensure a more valid assessment of nutrient intake; T2DM is more diet and lifestyle related in comparison to T1DM. Data was not collected on the days that T1DM patients attended the clinic. Patients less than 18 years were also excluded to ensure alignment to ethics and study objectives. Those with missing information in the questionnaires due to not taking part wholly in responding to questions were excluded from data analysis.

3.3 Study Design

The cross-sectional study will be conducted as a case-control study.

Cases in these study refer to the study subjects with T2DM having blood glucose levels that are above the target blood glucose level ranges suggested by NICE, that is, 8.5 mmol/L.

Table 3: NICE Recommended target blood glucose level ranges

Target Levels by type	Before Meals (pre-prandial)	2 hours after meals (post-prandial)	Random (casual)
Non-diabetic	4 to 5.9 mmol/L	Under 7.8 mmol/L	Levels vary depending on when and how much you ate at your last meal. In general: 4.4–6.6 mmol/L before meals or when waking up; 5.5–7.7 mmol/L at bedtime
T2DM	4 to 7 mmol/L	Under 8.5 mmol/L	
T1DM	4 to 7 mmol/L	Under 9 mmol/L	
Children with T1DM	4 to 8 mmol/L	Under 10 mmol/L	
Note: There are differing opinions about the ideal blood glucose level range			

Controls in the study refer to study subjects whose blood glucose levels lie in the range suggested by the NICE guidelines, as shown above, that is under 8.5 mmol/L (**Table 3**). The study starts with an outcome (glycemic control), and then traces back to study and investigate exposures.

A sample size of 157 study subjects was purposively selected so as to yield statistically significant results. This is based on calculations using the G-Power sample size calculator for the t-test family as the study mainly focuses on comparing different variables between the good and poor glycemic control group. Using α value of 0.05 and a 1-β value of 0.84 (80% power), the test yielded 71 subjects in each group, totaling to approximately 142 study participants. The study was forwarded for approval to the relevant institutions and conducted in KNH during the period between July to September 2014.

3.4 Ethical Considerations

Approval to conduct the study was first sought from the UZ Ghent – Bimetra Clinics. The study was approved and given a project number EC/2014/0615. The proposal, informed consent form, and questionnaire were then forwarded to the KNH/UON -Ethics and Research Committee in Kenya. Upon review, the proposal was approved and issued an approval number,

P457/07/2014. The study was then registered with the KNH Department of Research and Programs, and the principal investigator made a commitment to share the research findings with KNH.

3.5 Data Collection

a. Questionnaire

A validated questionnaire was used to collect the patients with diabetes' personal information and dietary data, that is, the Diabetes History form used by the Michigan Diabetes Research and Training Center (MDRTC). The tool allows a few additional questions included in the DMH appendices, which can be included in the existing section of the main instrument. The survey instrument is designed to be researcher administered (**Appendix 1**). Its use was justified as it would ensure completeness and correctness of the data entered. Also, not all patients coming to Kenyatta are fluent in English.

Personal information collected was on age, residence town, estimated monthly family incomes, previous and current nutrition habits, historical data on personal health, family health and social behaviours.

Dietary information collected included diet intake composition, dietary adequacy, compliance with diet prescription, dietary diversity, meal frequency, and high fat/high cholesterol food use.

The questionnaire used is a validated questionnaire by MDRTC. Some minor adjustments were however made to enable easier understanding of the questions in the Kenyan setting. Some answer options were also added to the multiple choice type questions.

b. Anthropometric Measurements

To assess the nutritional status of the patients, their anthropometric measurements (height, weight, and waist) were taken.

- Height: The standard hospital height boards were used for all the subjects (to the nearest cm unit).
- Weight: One calibrated electronic scale was used for all the subjects (to the nearest 0.5 kg). Weight was measured in light indoor clothing.

Table 4: Nutrition Status

BMI	Nutritional status
Below 18.5	Underweight
18.5–24.9	Normal weight
25.0–29.9	Pre-obesity
30.0–34.9	Obesity class I
35.0–39.9	Obesity class II
Above 40	Obesity class III

Source: Adapted from WHO-Europe, 2015

Body Mass Index (BMI) was then obtained from the formula: BMI = weight (kg)/height (m^2). Data was entered in SPSS version 22. Classification of BMI was made, and subjects placed into different categories based on the WHO-Europe 2015 (**Table 4**) recommendations for adults over 18 years old.

- Waist circumference: was determined using a plastic tape measure (to the nearest cm unit). Sex-specific waist circumference cut-offs were used to depict the risk of metabolic complications associated with obesity. A table based on the increased relative risk observed in the Netherlands from a random sample of 2183 men and 2698 women aged between 20–59 years (Han et al., 1995) was used by the WHO. However, the sex-specific cut-off points cited in the report of the WHO Expert Consultation on Obesity (2000b) are only an example and not WHO recommendations (**Table 5**). In such they will be used for classification this study only to indicate convincing evidence.

Table 5: WHO cut-off points and risk of metabolic complications

Indicator	Cut-Off Points	Risk of metabolic complications
Waist circumference	>94 cm (M); >80 cm (F)	Increased
Waist circumference	>102 cm (M); >88 cm (F)	Substantially increased

Note**: M: Male; F: Female **Source: WHO

c. Assessment of glycemic control

Since the clinic did not conduct routine HbA_{1C}, the blood glucose levels of the patients recorded were as per the test conducted, mostly a post prandial test. The NICE guidelines for glucose ranges for the various blood glucose tests will be used to define, for example, good glycemic control (**Table 3**).

All the measurements obtained were recorded on spaces provided in the questionnaire.

d. Assessment of dietary intake

The 24-hour dietary recall procedure was conducted to obtain and estimate dietary intake. Data on specific foods taken and estimation of portion sizes were collected. Measurement guides such as count/number; volumes (1 cup, ml); and, sizes (small to large) were used to approximate portion sizes. Household measures were also referred to for estimation where common utensils of known volume used. These included kitchen utensils of known volume such as a plate, serving spoon, teaspoon, saucer, and, tablespoon were used to aid in portion size estimates.

The data on food was entered onto SPSS vs. 22 and the portion size then converted to gram estimates. The daily nutrient intake (g/day) was the obtained for each food type composing the total meals consumed during the particular day. The daily nutrient intake was then converted to the daily nutrient intake (kcal per day) and later individual nutrient intakes (protein, carbohydrate and fat) added up to give the total daily energy intake (kcal per day) estimates.

e. Assessment of other risk factors and disease management practices

3.6 Data and Statistical Analysis

Statistical analysis was conducted using SPSS vs. 22 statistical software. Descriptive statistics such as mean, median, standard deviation e.t.c., and frequencies were calculated. Associations between variables were also assessed. Where appropriate, Pearson correlation coefficients were used to report measures of correlation between variables.

Two sample t-test was used to compare anthropometric and blood glucose data between genders. It was also used to assess diabetes management practices such as frequency of hospital

visits, diabetes educator/dietician encounters, urine analysis, insulin use, meal plan use and occurrence of DKA in the two different groups of study subjects.

In this study, the dietary behavior of study subjects was assessed using a 24-hour dietary assessment. Total energy (kcal/day) and nutrient densities (%) were computed for every individual to aid in the assessment of dietary compliance of the subjects based on recommended intake levels.

The chi-square test was used to assess statistical significance of the difference in the percentages of good or poor glycemic control, according to various independent categorical variables. A regression analysis was used to assess the predictors of glycemic control on independent variables like behavioural and some clinical risk factors. The validity of using a binary logistic regression model was tested. Odd's ratios and the associated p-value were reported. Parameter selection was not considered as risk factors for T2DM reported have been established by previous studies (Chege, 2010). ANOVA analysis was conducted to analyse multi-level variables associated with glycemic control. A p-value <0.05 was considered statistically significant.

4.0 CHAPTER FOUR: RESULTS

This chapter describes the quantitative and qualitative findings of this study.

4.1 Participant Characteristics

Several variables of interest were obtained from the questionnaire. Socio-demographic characteristics included gender, weight, height, age, monthly income, education level, alcohol intake, and smoking status. Diabetes-related characteristics included the duration of diabetes, family history of diabetes, and the presence of DKA. Diabetes self-care behaviors variables are related to medication/insulin, adherence to a meal plan, and dietary intake. Dietary and lifestyle modifications variables are related to meals and snacks, meal-planning methods and diet restrictions. The general attitude and satisfaction variables are related to patients' experience at health provision centres, motivation by a health care provider, coming to appointments, and consultation and advice received by health care providers at the clinic.

A sample of 157 T2DM patients took part in the study, and their characteristics are summarized in **Table 6**. The mean Body Mass Index (BMI) of the sample was 32.24kg/$m^{2.}$ Being characterized by a high proportion of overweight and obesity (≥30 kg/m^2) with the latter proportion accounting for 61.1% of the total study population. 49.1% of the population had attained up to tertiary level (college or university) education. The majority of the study population had visited either a dietician (73.2%) or a diabetes educator (93.6%). However, only 54.1% reported having received education on a diabetic meal plan or diet, and an even lower self-reported diet compliance level of 20.4% was recorded.

Table 6: Patient Characteristics

A. Personal Information

Number (N, male/female)	157	(75;82)
Age Groups (years) (%)		
	≤35 years	6.4
	35 to 44 years	8.3
	45 to 54 years	26.8
	55 to 64 years	38.2
	65 to 70 years	20.4
Body Mass Index (kg/m^2)		Mean and std. deviation
	Study population	32.24 ± 7.163
	Male	30.47 ± 6.755
	Female	33.87 ± 7.178

Normal (18.5 to 24.9) (%)	14.7	
Overweight (25.0 to 29.9) (%)	22.8	
Obese (≥30) (%)	61.1	
Waist circumference		Mean and std. deviation
	Study population	115.45 ± 27.025
	Male	108.68 ± 21.559
	Female	119.88 ± 27.159
Increased risk of metabolic complications (>94 cm (M); >80 cm (F)) (%)	73.3 (M); 96.3 (F)	
Substantially increased risk of metabolic complications (>102 cm (M); >88 cm (F)) (%)	58.7 (M); 91.5 (F)	
Blood glucose levels		Mean and std. deviation
	Study population	9.78 ± 5.067
	Male	9.443 ± 4.58
	Female	10.089 ± 5.490
Grouping based on glycemic control		Mean and std. deviation
≤8.5mmol/L		6.4 ± 1.4
>8.5mmol/L		13.6 ± 5.0
NICE Recommended target post-prandial blood glucose level range (Under 8.5mmol/L) (%)	54.7	

B. Socio-economic characteristics

Education status (%)		
	Primary	8.9
	Secondary	33.1
	Tertiary (College and University)	49.1 (40.1;9.6)
	No formal education attended	8.3
Estimated monthly income (%)		
	Ksh. 10,000 and below	8.3
	Ksh. 10,001 to 20,000	25.5
	Ksh 20,001 to 50,000	39.5
	Ksh 50,001 to 80,000	23.6
	Ksh 80,001 to 100,000	2.5
	Ksh 100,001 and above	0.6

C. Clinical Characteristics

First-degree relatives with diabetes (%)	Yes	47.1
Use of Insulin (%)	Yes	40.1
Use of metmorphin (%)	Yes	3.2
High cholesterol medication (%)	Yes	8.9
Vitamin supplements (%)	Yes	6.4
Herbal medications (%)	Yes	5.7
Hospitalized for DKA (%)	Yes	24.8

D. Behaviour characteristics

Visit to a dietician (%)	Yes	73.2
Visit to a diabetes educator (%)	Yes	93.6
Educated about a diabetic meal plan or diet (%)	Yes	54.1
Self-reported diet compliance (%)	Yes	22.3
Smokers (%)	Yes	15.3
Alcohol consumers (%)	Yes	12.1

Data analysis was based on the classification of the study participants into two groups (good and poor glycemic control groups) based on their blood sugar levels. The group with good glycemic control had 83 (54%) subjects while 74 patients had not attained the recommended blood glucose levels. On this basis disease management practices, anthropometry and blood glucose data, satisfaction levels, dietary practices and diabetes' risk profile was examined.

4.2 Disease Management Practices

The mean number of total visits made to health care providers was reported to be similar in both groups. A mean of 3 visits in the past 12 months from the time of data collection was recorded with 61.4% and 66.2% of individuals with good glycemic control and poor glycemic control respectively having made 3 hospital visits.

The majority of the study subjects reported having seen a dietician at a point in time. 28.9% and 24.3% individuals with good glycemic control and poor glycemic control respectively (42 study subjects) had never had an encounter with a dietician. Of this, it was seen that individuals with poor glycemic control had a higher proportion of 32.4% (versus 22.9%) of more recent visits within the last 12 months.

The unit (Clinic 17) has medical personnel working as diabetes educators. As such, the findings indicated that that there was no statistical significant difference in the group with good

glycemic control (1.2±0.5 visits) compared to 1.27±0.6 visits recorded in those with poor glycemic control.

All study subjects had given a urine sample for urine analysis in the past twelve (12) months from the time of data collection. Only 8.9% of the total study population conducted their blood sugar tests. There were no significant statistical differences in the periods that both the HbA_{1C} {t(155)=0.7; p=0.5} and cholesterol blood tests { t(155)=0.1; p=0.9} were conducted for both groups at a 5% significance level in groups.

A higher proportion of individuals from the group with poor glycemic control were found to be using insulin (50% compared to 31.3%). Correlation using the 2-sided Fischer's exact test showed a significant association between use of insulin and classification as per glycemic control at a 95% confidence interval; p=0.03. Individuals in the group with poor glycemic control recorded a higher mean of nights that they spent as patients while hospitalized. They had a mean of 5±7.4 nights compared to a mean of 4±6.2 nights recorded for the group with good glycemic control. They also had a higher proportion of individuals who had ever been hospitalized for DKA; 60.8% compared to 51.8%.

4.3 Attitudes and Satisfaction Levels

151 of the study subjects reported to be receiving their health care by clinical officers and/or nurses. The most important reason that the majority of the study subjects (51%) came to the diabetes outpatient clinic is due to advice by health care providers. This was so that they could get more specialized attention (42.7%).

Table 7: Satisfaction Levels of study participants

	≤8.5mmol/L n=83	**>8.5mmol/L n=74**	**Pearson chi-sp. p-value**
Satisfied with diabetes care provided %(score)	50.6(5)	40.5(5)	0.6
Diabetes care provided could be better %(score)	53(5)	41.9(4)	0.0*
Diabetes care provided in last few years just about perfect %(score)	53(5)	32.4(2)	0.0
Certain things about care received could be improved %(score)	48.2(5)	47.3(4)	0.4

(1) Strongly Disagree; (2) Disagree; (3) Not Sure; (4) Agree Strongly; (5) Agree
**:p-value obtained from Fischer's exact test*

Of relevance to this study were some problems the subjects reported to be difficult in their disease management. These includes diet-related problems recorded by 30 study subjects. 3.6% of the participants who reported to be consuming alcohol (13.4%) cited cessation of this habit as a difficult problem. 14 out of the total 21 study subjects who recorded alcohol intake were from the group with poor glycemic control.

4.4 Dietary intake of T2DM patients

4.4.1 Consumption of Food Groups

A total of eleven major food groups was adopted from the Kenya Nutrition Profile (Food and Nutrition Division FAO, 2005). The foods reported by the study subjects were placed in these different food groups based on similarities in nutritional composition or biological specifications. The major food groups in Kenya are as listed below:

- Cereals and cereal products (excl. beer)
- Fruit and vegetables
- Milk, milk products, and eggs
- Starchy roots, tubers, and bananas
- Sugars and Sweeteners; soft, carbonated and flavoured drinks
- Pulses, legumes, nuts, oil crops
- Meat and meat products; offals
- Other: black tea, water
- Vegetable oils
- Fish, seafood
- Animal fats

Frequencies were calculated to assess the amounts of each food group comprising either breakfast, lunch, supper, and snacks. On average, carbohydrates were largely consumed throughout the day.

Table 8: Overall food group consumption

% consumption	Breakfast	Mid-morning	Lunch	Afternoon	Supper
Cereals and cereal products (excl. beer)	20.8	18.7	29.5	27.8	25.4
Fruit and vegetables	3.4	17.0	33.4	18.1	29.2
Milk, milk products and eggs	27.6	22.0	1.7	21.4	4.9
Starchy roots, tubers and bananas	6.6	7.3	6.2	2.4	3.0
Sugars and Sweeteners; soft, carbonated and flavoured drinks		1.3	0.7	6.7	
Pulses, legumes, nuts, oil crops	0.4	0.4	15.3	1.5	18.5
Meat and meat products; offals	0.4	1.5	7.1	3.6	11.0
Other: black tea, water	4.7	0.2	0.7	3.9	
Vegetable oils			2.2	14.0	
Fish, seafood			0.7		5.6
Animal fats		3.9			

4.4.2 Comparison between consumption of the different food groups

Patients with a good glycemic control (n=83) versus those with a poor glycemic control (n=74) were then compared in terms of mean percentage consumption of the different food groups. Based only on percentage values, subjects in the poor glycemic control had higher consumption of starchy root tubers, meat products, and cereals.

Table 9: Food group consumption in the different groups

	≤8.5mmol/L	>8.5mmol/L
Cereals and cereal products (excl. beer) (%)	21	24
Fruit and vegetables (%)	20	21
Milk, milk products and eggs (%)	15	14
Starchy roots, tubers and bananas (%)	4.2	6.4
Sugars and Sweeteners; soft, carbonated and flavoured drinks (%)	1.8	1.6
Pulses, legumes, nuts, oil crops (%)	6.2	9.0
Meat and meat products; offals (%)	3.4	5.9
Other: black tea, water (%)	1.7	1.7
Vegetable oils (%)	4.5	0.8
Fish, seafood (%)	1.4	3.3
Animal fats (%)	0.9	0.7

4.4.3 Energy Intake

The data showed no significant differences in the diet consumed by the study subjects when split into the group with good glycemic control and that with poor glycemic control (95% CI). The results of their dietary intake were thus assessed using the food estimates from the 24-hour recall for the entire study population (**Table 10**).

2016kcal/day was the mean reported energy intake of the study subjects. The American Diabetes Association (2008) recommends energy intake in the range of 1000-1200kcal/day and 1200-1600kcal/day for overweight and obese females and males respectively aimed at some weight reduction. This shows that the study subjects mean energy intake value exceeds the recommended daily energy intake to bring about a reduction in weight. 83.9% of the study population were characterised as being overweight and obese.

It is recommended that the proportion of energy obtained from carbohydrates, protein and fat in the diet of diabetic patients is in the ratio of 50/20/30as shown in the table below. The table below reports the percentage of energy from the reported by the study subjects. It is in the ratio of 53/23/23. The mean carbohydrate and protein intake of 269g and 118g per day.

Table 10: Nutrient intake assessed from 24-hr recall food estimates

Food Group	Mean±S.D
Carbohydrates(g)	269 ± 123
Protein(g)	118 ± 36
Fat(g)	52 ± 30
Total energy intake(kcal/day)	2016 ± 849

Source: Mark and Mary (2008), adapted from The American Diabetes Association

	Nutritional recommendations T2DM	Mean
Carbohydrate (E%)	50-60	53
Protein (E%)	10-20	23
Fat (E%)	20-30	23

4.5 Diabetes risks profile

Statistically, significant differences were seen in the mean of both BMI and waist circumference measures tested at 5% significance level between the two genders; p=0.003 and p=0.005 respectively. The mean BMI and waist circumference measures of females were higher than that in females. Consequently, a frequency table indicated that a higher proportion of females in the study (49%) had a poor glycemic control compared to the male subjects (45%). Based on the findings we could however not conclude that the mean blood glucose levels of the two genders was different on a 95% confidence interval; p=0.7.

Table 11: Anthropometry and Blood Glucose data

	BMI±SD (kg/m^2)	Waist±SD (cms)	Blood Gluc. ±SD (mmol/L)
Male (n=75)	30.5 ± 6.8	109 ± 22	9.4 ± 4.6
Female (n=83)	33.9 ± 7.2	120 ± 27	10.1 ± 5.5
p-value*	0.003	0.005	0.668

***: obtained from an independent samples t-test at a 95% confidence interval**

Similar to studies conducted compiled by a WHO Expert Consultation (Geneva, 8–11 December 2008), our study showed that people in the higher glycemic control had higher mean values of BMI and waist circumference (cms).

Table 12: Risk Profile Summary table

Parameter	Blood glucose classification ≤8.5mmol/L (N=83)	>8.5mmol/L(N=74)	Independent t-test p-value
First-degree relative			0.001
Yes n(%)	30(36.1)	46(66.2)	
No n(%)	53(63.9)	28(37.8)	
BMI (kg/m^2)	31.373±6.786	33.219±7.489	0.107
Waist (cms)	114.06±28.115	121.75±17.944	0.04
Self-reported dietary compliance			0.04
Do not know n(%)	11(13.3%)	6(8.1%)	
Yes n(%)	23(27.7%)	12(16.2%)	
No n(%)	49(59%)	56(75.7%)	
Alcohol use			0.00
Yes n(%)	2(2.4)	17(23)	
No n(%)	81(97.6)	57(77)	
Cigarette smoking			0.011
Yes n(%)	7(8.4)	17(23)	
No n(%)	76(91.6)	57(77)	

The association between BMI and waist circumference; and T2DM has been widely in many studies even after controlling for age, smoking and family history (Qiao & Nyamdorj, 2010b). The differences in the mean waist circumference of the two groups were found to be statistically significant at a 5% significance level. Despite showing no statistical significant difference in the mean BMI, the study found that those with poor glycemic control had a higher mean BMI value when compared to those with good glycemic control (**Table 12**).

From the results, the patients in the two groups showed variability in blood glucose levels for self-reported dietary compliance. Statistical significance of differences in compliance were seen for the two groups at a 5% significance level: p= 0.04. 27.7% of the patients with good

glycemic control reported diet compliance as compared to 16.2% in the poor control group. About 10.8% (17subjects) of the total patient population, however, did not know whether their diet record complied with recommendations given during nutrition counselling (**Table 12**).

A binary logistic regression of glycemic control was conducted on the following independent variables: family; alcohol use; cigarette smoking; self-reported dietary compliance; weight; BMI and, waist circumference. The model showed that there was some predictive capacity in the regression equation and predicted that approximately 33.4% of the variability in glycemic control was accounted for by the independent variables (Nagelkerke R^2=0.334). The predictors first-degree relative with diabetes mellitus; weight, BMI, waist circumference and alcohol use were found to be statistically significant predictors in the regression equation model.

Table 13: Parameter estimates from the binary logistic regression of glycemic control on some risk factors of T2DM

Variable	Odds Ratio	p-value
Family	0.324	0.003
Weight(kg)	0.957	0.009
BMI(kg/m^2)	1.123	0.005
Waist circumference (cms)	1.018	0.044
Alcohol use	10.040	0.005
Cigarette smoking	2.219	0.159
Self-reported dietary compliance	1.512	0.135

A one-way ANOVA analysis was used to assess the dependent continuous blood glucose level values on some independent categorical covariates with more than two levels (age, income, and, educational background). The test revealed significant results only for age (p=0.04) to show that the variances within each age-group were statistically different from each other.

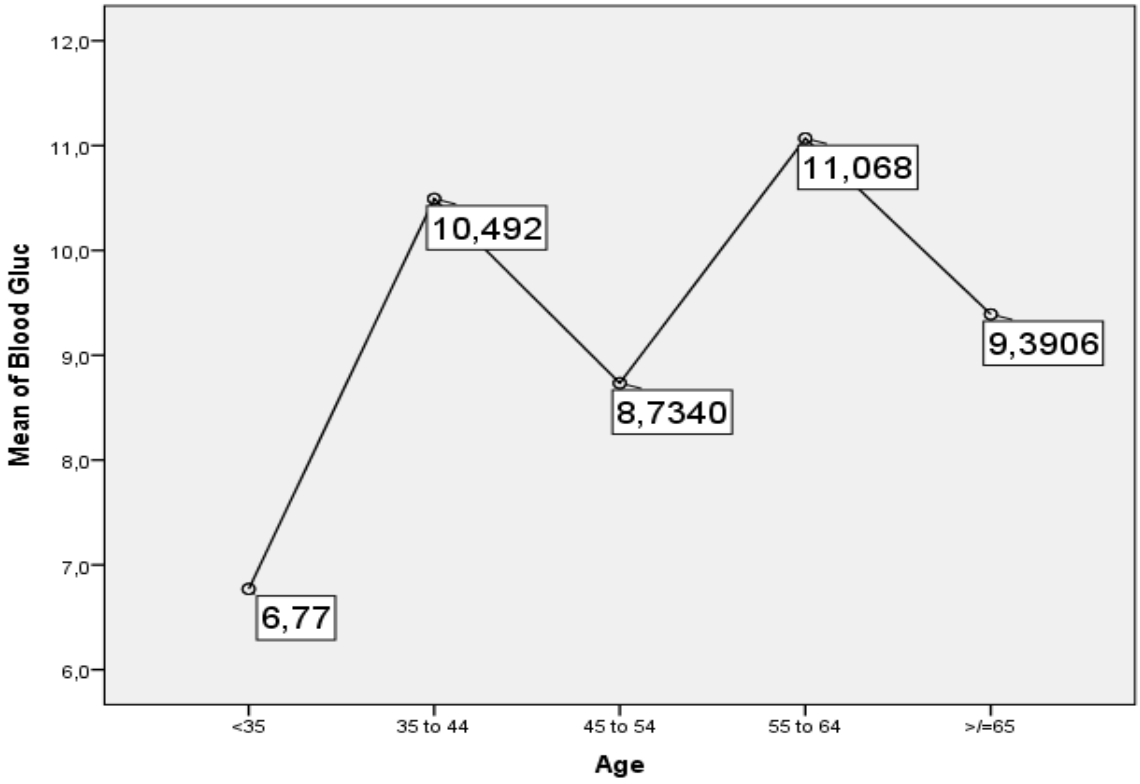

Figure 2: ANOVA table of mean blood glucose levels per age-group

Note: X-axis: Age (years); Means of Blood Glucose (mmol/L)

5.0 CHAPTER FIVE: DISCUSSION

This study was carried out at the KNH Diabetes Outpatient Clinic to compare type 2 diabetics having good and bad glycemic control. The aim was to identify the characteristics that were different among the two groups and whether these could be risk factors for their glycemic control. The study was driven by the apparent rapid rise in the prevalence of T2DM among Kenyans according to population surveys conducted by the Diabetes Management and Information Center (DMI) based in Nairobi, Kenya. The findings obtained show some differences in the disease management practices of patients in the two different groups based on their glycemic control during the period of data collection. Most of the study participants had an estimated monthly income between Ksh.10,000 to Ksh.50,000. The study participants had on average high literacy levels. This was coupled with a large population of all the participants having made a visit to either a dietician or diabetes educator. More than half of the study subjects admitted to have received education about a diabetic meal plan or diet at one point in time. Despite this, self-reported diet compliance was low. Most of the subjects had problems in self-management and adherence to nutrition as suggested by records from the 24-hour dietary recall, BMI and probably even waist circumference measurements. The results provide evidence that not all patients had optimal disease management and dietary practices.

5.1 Diabetes Management Practices

The majority of the study subjects reported having received diabetes education regarding lifestyle changes (diet-related and maintaining an active lifestyle) and the importance of observing clinic days. Care given to the patients is mostly by trained and certified clinical officers (CO's) and/or nurses. These are the main health care service providers in public hospitals in the Kenyan health system.

Individuals from both groups showed no statistical significant difference in the mean number of hospital visits in the past year (3 visits) prior to the period of data collection. Those in the group with bad glycemic control, however, had a higher proportion of individuals making this visits. They also reported a higher number of recent visits to a dietician and/or diabetes educator. This can be explained by the fact that patients who have not attained the recommended target blood glucose levels make this visits with the aim to get more counsel/ practical approaches so as to meet the targets.

Diabetic ketoacidosis which is characterized by hyperglycemia is more frequent in the individuals with poor glycemic control compared to those with good glycemic control .This contributed to their higher mean number of nights spent hospitalized overnight in a hospital. Diabetic ketoacidosis occurs primarily in type 1 diabetes mellitus patients but can also occur in patients with type 2 diabetes mellitus during periods of severe stress. This is in line with a study conducted by Edo, 2012 where he found concluded that DKA was common in Nigerian patients with T2DM. The finding of many cases of DKA (ketosis-prone T2DM) among patients with poor glycemic control has also been reported by other researchers (Ogbera A.O., 2007; 2009). Association was found between insulin usage and glycemic control. Those with poor glycemic control were found to have a higher usage of insulin therapy. Studies have shown that type 2 diabetes can be controlled through losing weight, improved nutrition, and exercise alone. However, in some cases, these measures are not enough and either oral medications and/or insulin must be used (The University of Chicago Medical Centre, 2015).

5.2 Diabetes risks profile

Similar to studies (CDC, 2009), our study showed that on average, women have higher BMIs compared to the male population (**Table 7**). The findings are also in line with those presented in **Fig. 1**. The association between BMI and T2DM has been widely established where higher T2DM rates and its complications were predicted with an increasing BMI (Khattab, 2010). In our finding, patients with poor glycemic control had a higher mean BMI (**Table 11**). 61.1% of the participants had a mean BMI $\geq$30 kg/m^2. However, this data may be biased as it was collected from one hospital in an urban setting, and the women sampled were from only one ethnic group. Similar results were obtained by Mendez et al., (2005), where rates as high as 69.9% for overweight (BMI $\geq$25 kg/m^2) were obtained from women residing in urban areas, using data obtained from 36 developing countries (Kenya included) over an eight-year period.

A statistical significant difference in the mean waist circumference between the two groups was inferred at a 5% significance level (p=0.04). Studies previously conducted (Yoshida and Okosun, 2002) argued that physiologic factors are important in diabetes control where they have showed the association between glycemic control and waist circumference. However, Hartz et al. (2006) suggested that patient factors such as understanding of diabetes and adherence to recommended behaviors and not physiologic factors are primary important

factors in gaining control over glycosylated hemoglobin. The significant association between waist circumference and glycemic control in this study is in line with previous cross-sectional studies that show also possible association and the strength of evidence may be considered as possible (European Journal of Clinical Nutrition, 2010b). All these studies have provided evidence that waist circumference predicted an association with diabetes and poor glycemic control independent of other factors. Waist circumference is often used as a proxy measure of abdominal adipose tissue, in particular, visceral adipose tissue (VAT) in clinical settings. VAT has been reported to create a greater risk of developing obesity-related disorders than subcutaneous adipose tissue (SAT) (Fox et al., 2007).

The findings revealed overall low rates of self-reported compliance to recommended dietary patterns (**Fig 3**) with higher frequencies of the predictor being seen in the poor glycemic control group (**Fig 4**).

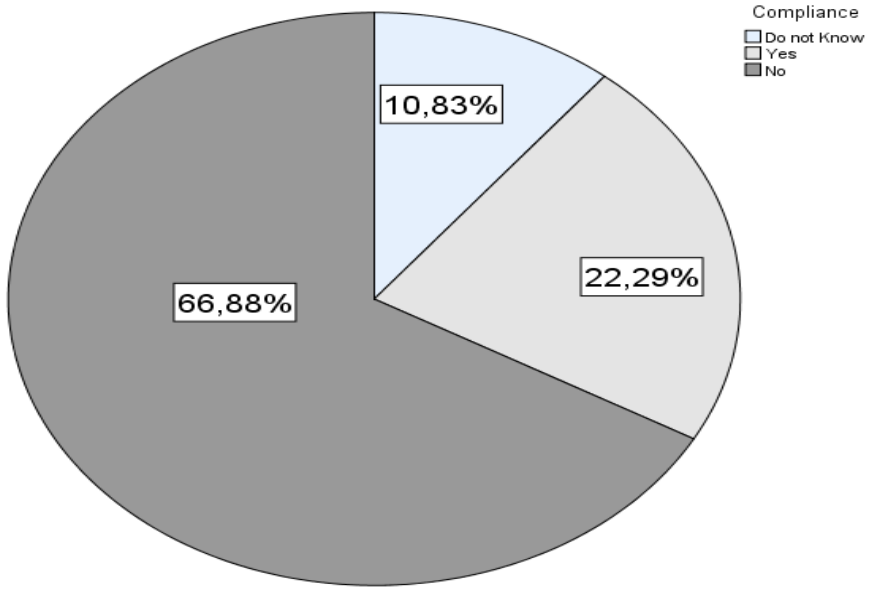

Figure 3: Pie chart for self-reported dietary compliance

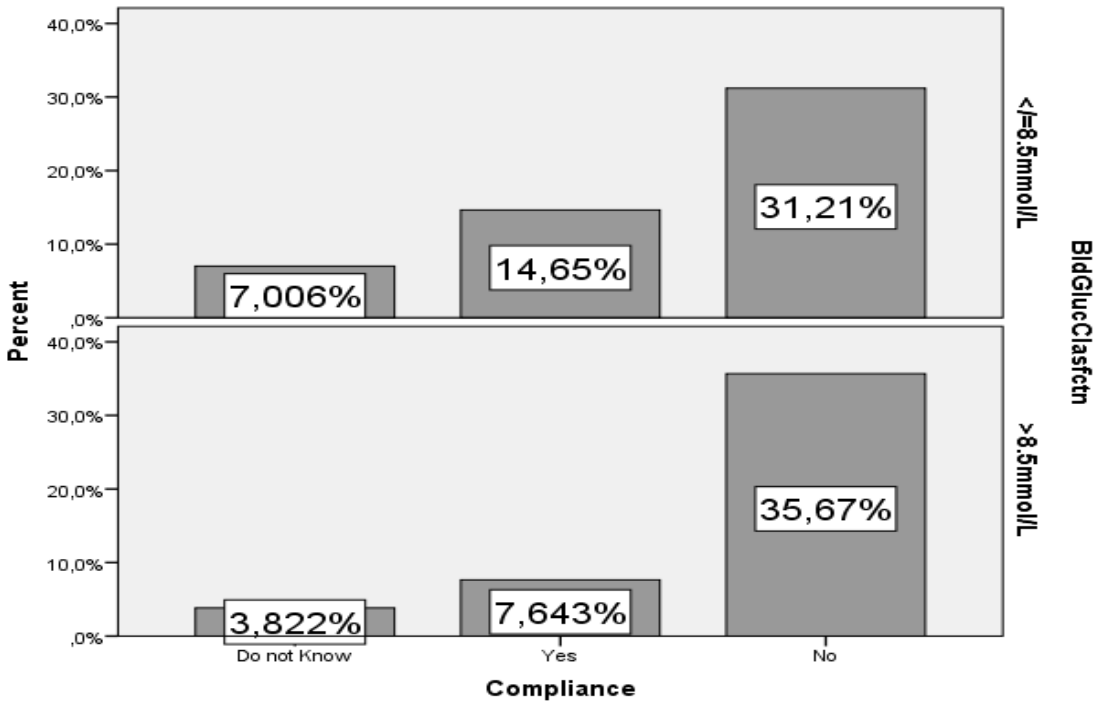

Figure 4: Self-reported dietary compliance versus glycemic control

The above findings are in line with (Alan, 2006) suggests that compliance or adherence problems are common problematic constructs in diabetes management. It can be due to various reasons such as demographic, psychological, social, health care provider and medical system, and disease- and treatment-related factors. A book by (Haynes, Taylor, & Sackett, 1979) acknowledges that non-adherence rates for chronic illness regimens and lifestyle changes are approximately 50%.

Our results are also in line with some studies that observed family history of T2DM to a significant independent risk factor of T2DM (Elbagir, Eltom, Elmahadi, Kadam, & Berne, 1996). Alcohol consumption and cigarette consumption was found to be higher among the subjects with poor glycemic control. The findings are in line with those from research conducted by (Ameena T. Ahmed, 2008) showing that alcohol consumption is inversely associated with glycemic control among diabetes patients. This supports current clinical guidelines for moderate levels of alcohol consumption among diabetes patients. As glycemic control affects incidence of complications of diabetes, it may translate into lower risk for complications

The age 55-64 age group had the highest mean blood glucose level (11.1mmol/L) showing average poor glycemic control. The under 18<x<35years of age has the lowest mean blood glucose level at 6.8mmol/L, that is indicative of good glycemic control for the group (**Fig. 2**). The findings are similar to those from a study by (Ben, et al., 2006).

5.3 Diet and T2DM

The distribution of calories recommended for T2DM patients is as shown in **Table 10**. The carbohydrate, protein, and fat was in the proportions of 53:23:23 and resembles the American Diabetes Association guidelines. The participants nutrient density is not very variable from recommendations by Carmen (2004) that energy proportions should be in the ratio of 50:20:30. However, the role of under-reporting which is characteristic of self-reported data cannot be overlooked. Administration of a self-reported food intake questionnaire may lead to under-reporting of usual intake amounts and this does not give actual dietary and lifestyle practices.

The main sources of carbohydrates in this study were starchy foods (ugali); starchy roots, tubers, and bananas; refined cereals (rice and wheat); biscuits and chips. Ugali was the most common starchy food and especially among the Ksh.10,000 to Ksh.20,000 income group. Rice was the more common carbohydrate group among the Ksh.20,000 to Ksh.50,000 monthly income. A major shift of food consumption from traditional grain to increased intakes of refined cereals has been reported in Kenya (Kenya National Nutrition Action Plan 2012-2017). This is also as reported in this study where increased consumption of rice and bread was seen in all income groups. Ugali is a cornmeal served at lunch and supper that is pure carbohydrates. Most Kenyans eat white ugali, and it is not uncommon for a Kenyan to consume it every day in massive quantities. The health benefits from white ugali are minimal with its main purpose being to provide quick energy and fill the stomach. In a city, energy expenditure is not very high due to the large amounts of transportation, readily available goods and services and more sedentary work. The energy and filling effects are thus not as high essential due to the absence of physically demanding jobs. High intake of carbohydrates can be explained by the fact that one of the staple foods in Kenya is maize.

The mean percent energy intake from carbohydrates was found to be 53% and thus approximately within the recommended reference value. Some studies, however, suggest that

a slightly less than the recommended reference value, that is, 40% may be partially beneficial for weight reduction and hyperglycemia management (McAuley, 2006; JDCCGC, 2006).

With adequate insulin, protein has very little effect on blood glucose.The dietary reference intake (RDI) acceptable macronutrient distribution range is 10-25%. However, dietary intake of protein in individuals with diabetes is similar to the general population and should not exceed 20% (Melinda & Christian, 2008). The study participants had a 23% mean energy from protein. The amount is above the recommended intake. The main source of protein in their diets was plant-based. This was mostly from pulses and legumes. Results from our study are in line with findings by Chege, 2010. Studies have also shown plant protein to be low-quality protein due to indigestibility and reduced bioavailability of some essential amino acids.

5.4 Limitations of the study

The use of 24 hour recall and the relatively small sample size make the generalization of the results obtained from the study of the entire population in Kenya is not possible with this particular study. The record may not necessarily indicate regular food consumption patterns of an individual as this is bound to be different from day-to-day. The record, however, gives mean dietary intake values for the study participants which helps assess their compliance. The results can only be extrapolated if dependent on additional longer-term studies in which a minimum of two (2) days of 24-hour recall is conducted, with a randomly selected sample frame; large sample size; as well as, a pre-tested questionnaire. The food consumption data obtained during data collection depended mostly on recall. Recall bias is known to affect the accuracy of data and contribute to systemic error. To ensure the smooth flow of information and reduce this bias, the interviews were sometimes conducted in a discussion format, in which responses to questions in the questionnaire were noted without interrupting the flow of the conversation. Some subjects may have under-reported their usual intake. Common to all observational studies, the finding of this study may be less powerful than an experimental study in detecting the true effect of the measured outcome since the design may have not properly controlled for some possible confounding factors.

The purposive sampling frame adopted could be a source of sampling bias in the study. The study being an observational study may be less powerful in detecting the true effect of the

measured outcomes. This was a hospital-based study and results might not necessarily concur with those of a population study in the same community under other conditions. KNH hospital is a government hospital and thus charges much less than the private hospitals. Though its services are available for all, it is mostly accessed by the very poor in the community to middle-class individuals; and not necessarily the upper-class citizens.

5.5 Conclusion

From this study, it can be concluded that the T2DM patients attending the KNH diabetes' outpatient clinic have some different characteristics when classified based on glycemic control. This was in regards to disease management practices such as hospital visits and insulin use. The study also revealed the problems the patients undergo in the management of the disease. The mean energy intake of study subjects in both groups showed no statistical significant differences. The study showed that the mean nutrient intakes were in line with dietary recommendations. However, the mean BMIs of the study population indicates that the study subjects need to improve further their consumption habits aimed at the improvement of their dietary intakes (**Table 6**). Need for change and improvement of food consumption habits is further stressed by the low self-reported compliance to dietary recommendations despite the majority of the population having received some form of nutrition counselling at one time.

Although our data are drawn from a small non-probabilistic sample that cannot easily be generalized, they provide insights into various management practices of the disease and dietary habits unique to Kenyan patients. The findings thus can be used by health service providers for planning purposes aimed at further improvement of services offered at health centers. They also stress the role of the patients themselves in ensuring a good glycemic control. For this reason, the study supports the idea that mere contact with health service providers does not guarantee a change in understanding and interpretation of health, illness and health care (Mercado-Martinez & Ramos-Herrera, 2002). Further studies involving a country-wide community-based sample would be necessary to determine whether these findings can be generalized to a wider population.

5.6 Further Work

According to the study findings, it is our recommendation that for this rapidly growing segment of the Kenyan population, policy makers need to focus their attention on strategies that address not just communicable diseases but non-communicable diseases as well. The National Diabetes Program (A five-year program in partnership with Ministry of Public Health and Sanitation and funded by World Diabetes Foundation**)** implemented in 2010 was given the role to develop a national diabetes strategy and guidelines. These documents should be made widely available to the public. They should provide clear recommendations on consumption levels and frameworks for monitoring at the individual level, promote healthy food choices and lifestyles and support prevention of diet-related NCDs. Additionally, reasons for non-compliance and non-adherence to recommendations by patients should be addressed by future studies to provide more insight in this particular area.

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APPENDICES

APPENDIX 1: TABLES

Table 1: Diagnostic Tests and Glucose Cut-off Values

Diagnostic test	Normal	Pre-diabetes	Diabetes
Haemoglobin A1c	<5.7%	5.7 – 6.4%	≥6.5%
Fasting plasma glucose	<100mg/dL	100 - 125mg/dL	≥126mg/dL
Randomn plasma glucose	<130mg/dL	130 - 199mg/dL	≥200mg/dL
Oral glucose tolerance test	<140mg/dL	140 – 199mg/dL	≥200mg/dL
For A1c and fasting glucose, the diagnosis must be confirmed by a second test			
A random glucose ≥200mg/dL must be confirmed with fasting glucose ≥126mg/dL or the OGTT			

Source: WHO Guidelines, 2008

Table 2: Targeting and Monitoring Glycemic Controlling Patients with Diabetes

<table>
<tr><td colspan="2">Target A1c should be defined based on personal assessment of risks and benefits of treatment. Below are factors marked “*” or “**” where;

“*” = factors that limit the benefit of tight control

“**”= factors that heighten the risk of tight control.

Patients lacking any of these factors should generally have an A_{1C} of <=7%.

Patients having these factors should have a goal of minimizing symptoms of hyperglycemia and to control glucose as well as possible without incurring side-effects or excessive treatment burden; while an appropriate A1c is difficult to define exactly, treatment should be aimed to keep the A1c under 9%

HbA_{1C} should be measured every 3-6 months.

If HbA_{1C} is above goal:

5. Assess treatment regimen
6. Diabetes dietary counselling or referral
7. Start or increase medication
8. Recheck HbA_{1C} in 3 months</td></tr>
<tr><td>“*”: Factors limiting benefit of tight control

1. Comorbidities (e.g., end-stage cancer, severe heart failure).

2. Advanced diabetes complications (e.g., proliferative retinopathy, renal failure).

3. Inability to safely carry out treatment regimen.

4. Limited life expectancy</td><td>“**”: Factors heightening risk of tight control

1. History of severe hypoglycemia (inability to treat without assistance).

2. Hypoglycemia unawareness.

3. Advanced cardiovascular or cerebrovascular disease.

4. Autonomic neuropathy (especially cardiac).

5. Comorbidities that impair the detection of hypoglycemia (e.g., alteration in mental status, alcoholism, etc.).

6. Poor social support</td></tr>
</table>

Source: UM (The University of Chicago Medical Center, 2015)

Table 3: NICE Recommended target blood glucose level ranges

Target Levels by type	Before Meals (pre-prandial)	2 hours after meals (post-prandial)	Random (casual)
Non-diabetic	4 to 5.9 mmol/L	Under 7.8 mmol/L	Levels vary depending on when and how much you ate at your last meal. In general: 4.4–6.6 mmol/L before meals or when waking up; 5.5–7.7 mmol/L at bedtime
T2DM	4 to 7 mmol/L	Under 8.5 mmol/L	
T1DM	4 to 7 mmol/L	Under 9 mmol/L	
Children with T1DM	4 to 8 mmol/L	Under 10 mmol/L	

Note: There are differing opinions about the ideal blood glucose level range

Table 4: Nutrition Status

BMI	Nutritional status
Below 18.5	Underweight
18.5–24.9	Normal weight
25.0–29.9	Pre-obesity
30.0–34.9	Obesity class I
35.0–39.9	Obesity class II
Above 40	Obesity class III

Source: Adapted from WHO-Europe, 2015

Table 5: WHO cut-off points and risk of metabolic complications

Indicator	Cut-Off Points	Risk of metabolic complications
Waist circumference	>94 cm (M); >80 cm (F)	Increased
Waist circumference	>102 cm (M); >88 cm (F)	Substantially increased

Note**: M: Male; F: Female **Source: WHO

Table 6: Patient Characteristics

A. Personal Information

Number (N, male/female)	157	(75;82)
Age Groups (years) (%)		
	≤35 years	6.4
	35 to 44 years	8.3
	45 to 54 years	26.8
	55 to 64 years	38.2
	65 to 70 years	20.4
Body Mass Index (kg/m^2)		Mean and std. deviation
	Study population	32.24 ± 7.163
	Male	30.47 ± 6.755
	Female	33.87 ± 7.178
Normal (18.5 to 24.9) (%)	14.7	
Overweight (25.0 to 29.9) (%)	22.8	
Obese (≥30) (%)	61.1	
Waist circumference		Mean and std. deviation
	Study population	115.45 ± 27.025
	Male	108.68 ± 21.559
	Female	119.88 ± 27.159
Increased risk of metabolic complications (>94 cm (M); >80 cm (F)) (%)	73.3 (M); 96.3 (F)	
Substantially increased risk of metabolic complications (>102 cm (M); >88 cm (F)) (%)	58.7 (M); 91.5 (F)	
Blood glucose levels		Mean and std. deviation
	Study population	9.78 ± 5.067
	Male	9.443 ± 4.58
	Female	10.089 ± 5.490
Grouping based on glycemic control		Mean and std. deviation
≤8.5mmol/L		6.4 ± 1.4
>8.5mmol/L		13.6 ± 5.0
NICE Recommended target post-prandial blood glucose level range (Under 8.5mmol/L) (%)	54.7	

B. Socio-economic characteristics

Education status (%)		
	Primary	8.9
	Secondary	33.1
	Tertiary (College and University)	49.1 (40.1;9.6)
	No formal education attended	8.3
Estimated monthly income (%)		
	Ksh. 10,000 and below	8.3
	Ksh. 10,001 to 20,000	25.5
	Ksh 20,001 to 50,000	39.5
	Ksh 50,001 to 80,000	23.6
	Ksh 80,001 to 100,000	2.5
	Ksh 100,001 and above	0.6

C. Clinical Characteristics

First-degree relatives with diabetes (%)	Yes	47.1
Use of Insulin (%)	Yes	40.1
Use of metmorphin (%)	Yes	3.2
High cholesterol medication (%)	Yes	8.9
Vitamin supplements (%)	Yes	6.4
Herbal medications (%)	Yes	5.7
Hospitalized for DKA (%)	Yes	24.8

D. Behaviour characteristics

Visit to a dietician (%)	Yes	73.2
Visit to a diabetes educator (%)	Yes	93.6
Educated about a diabetic meal plan or diet (%)	Yes	54.1
Self-reported diet compliance (%)	Yes	22.3
Smokers (%)	Yes	15.3
Alcohol consumers (%)	Yes	12.1

Table 7: Satisfaction Levels of study participants

	≤8.5mmol/L	>8.5mmol/L	Pearson chi-sp. p-value
Satisfied with diabetes care provided (%)	50.6(5)	40.5(5)	0.6
Diabetes care provided could be better (%)	53(5)	41.9(4)	0.0*
Diabetes care provided in last few years just about perfect (%)	53(5)	32.4(2)	0.0
Certain things about care received could be improved (%)	48.2(5)	47.3(4)	0.4

(1) Strongly Disagree; (2) Disagree; (3) Not Sure; (4) Agree Strongly; (5) Agree
**:p-value obtained from Fischer's exact test*

Table 8: Overall food group consumption

% consumption	Breakfast	Mid-morning	Lunch	Afternoon	Supper
Cereals and cereal products (excl. beer)	20.8	18.7	29.5	27.8	25.4
Fruit and vegetables	3.4	17.0	33.4	18.1	29.2
Milk, milk products and eggs	27.6	22.0	1.7	21.4	4.9
Starchy roots, tubers and bananas	6.6	7.3	6.2	2.4	3.0
Sugars and Sweeteners; soft, carbonated and flavoured drinks		1.3	0.7	6.7	
Pulses, legumes, nuts, oil crops	0.4	0.4	15.3	1.5	18.5
Meat and meat products; offals	0.4	1.5	7.1	3.6	11.0
Other: black tea, water	4.7	0.2	0.7	3.9	
Vegetable oils			2.2	14.0	
Fish, seafood			0.7		5.6
Animal fats		3.9			

Table 9: Food group consumption in the different groups

	≤8.5mmol/L	>8.5mmol/L
Cereals and cereal products (excl. beer) (%)	21	24
Fruit and vegetables (%)	20	21
Milk, milk products and eggs (%)	15	14
Starchy roots, tubers and bananas (%)	4.2	6.4
Sugars and Sweeteners; soft, carbonated and flavoured drinks (%)	1.8	1.6
Pulses, legumes, nuts, oil crops (%)	6.2	9.0
Meat and meat products; offals (%)	3.4	5.9
Other: black tea, water (%)	1.7	1.7
Vegetable oils (%)	4.5	0.8
Fish, seafood (%)	1.4	3.3
Animal fats (%)	0.9	0.7

Table 10: Nutrient intake from 24-hr recall food estimates

Food Group	Mean±S.D
Carbohydrates(g)	269 ± 123
Protein(g)	118 ± 36
Fat(g)	52 ± 30
Total energy intake(kcal/day)	2016 ± 849

Source: Mark and Mary (2008), adapted from The American Diabetes Association

	Nutritional recommendations T2DM	Mean
Carbohydrate (E%)	50-60	53
Protein (E%)	10-20	23
Fat (E%)	20-30	23

Table 11: Anthropometry and Blood Glucose data

	BMI±SD (kg/m^2)	Waist±SD (cms)	Blood Gluc. ±SD (mmol/L)
Male (n=75)	30.5 ± 6.8	109 ± 22	9.4 ± 4.6
Female (n=83)	33.9 ± 7.2	120 ± 27	10.1 ± 5.5
p-value*	0.003	0.005	0.668

***: obtained from an independent samples t-test at a 95% confidence interval**

Table 12: Risk Profile Summary table

Parameter	Blood glucose classification ≤8.5mmol/L (N=83)	Blood glucose classification >8.5mmol/L(N=74)	Independent t-test p-value
First-degree relative			0.001
Yes n(%)	30(36.1)	46(66.2)	
No n(%)	53(63.9)	28(37.8)	
BMI (kg/m^2)	31.373±6.786	33.219±7.489	0.107
Waist (cms)	114.06±28.115	121.75±17.944	0.04
Self-reported dietary compliance			0.04
Do not know n(%)	11(13.3%)	6(8.1%)	
Yes n(%)	23(27.7%)	12(16.2%)	
No n(%)	49(59%)	56(75.7%)	
Alcohol use			0.00
Yes n(%)	2(2.4)	17(23)	
No n(%)	81(97.6)	57(77)	
Cigarette smoking			0.011
Yes n(%)	7(8.4)	17(23)	
No n(%)	76(91.6)	57(77)	

Table 13: Parameter estimates from the binary logistic regression of glycemic control on some risk factors of T2DM

Variable	Odds Ratio	p-value
Family	0.324	0.003
Weight(kg)	0.957	0.009
BMI(kg/m^2)	1.123	0.005
Waist circumference (cms)	1.018	0.044
Alcohol use	10.040	0.005
Cigarette smoking	2.219	0.159
Self-reported dietary compliance	1.512	0.135

APPENDIX 2: FIGURES

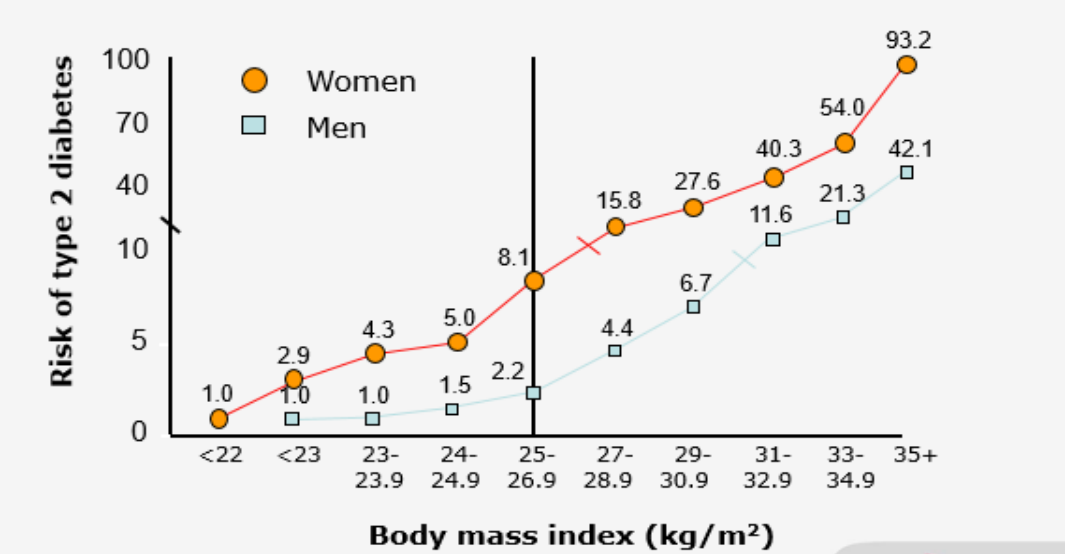

Figure 1: The relationship between BMI and the risk of developing type 2 diabetes
Adapted from Klein S and Romijn J, in Williams Textbook of Endocrinology, 10th ed, 2003

From the IDF publication: 'Diabetes and Obesity', p.25

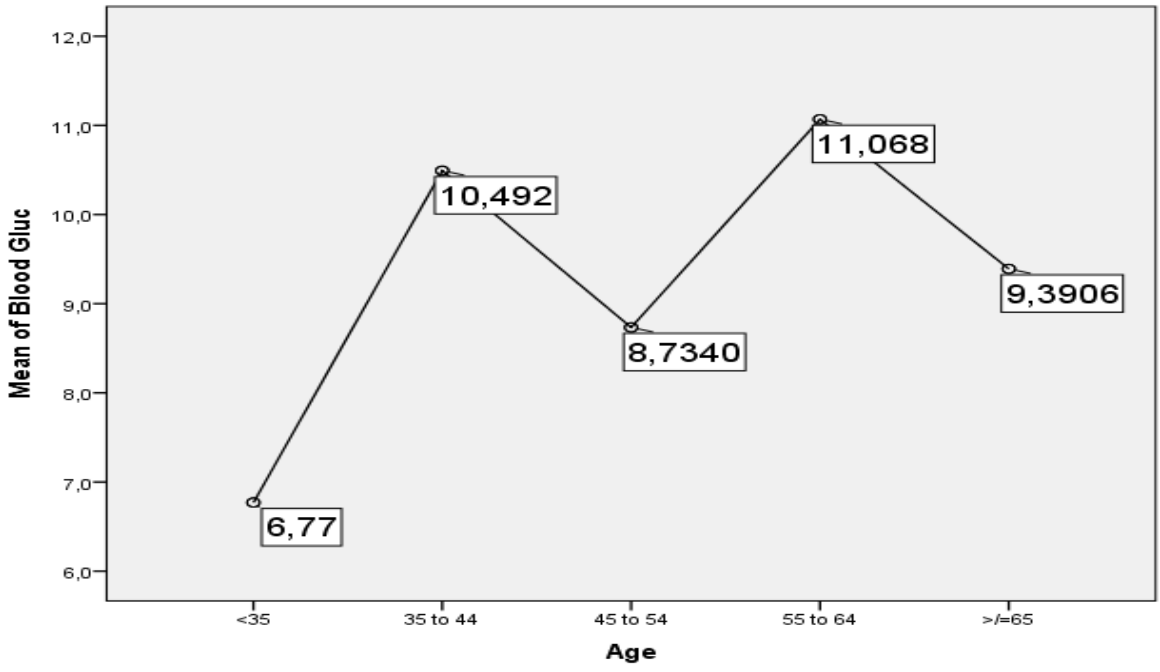

Figure 2: ANOVA table of mean blood glucose levels per age-group

Note: X-axis: Age (years); Means of Blood Glucose (mmol/L)

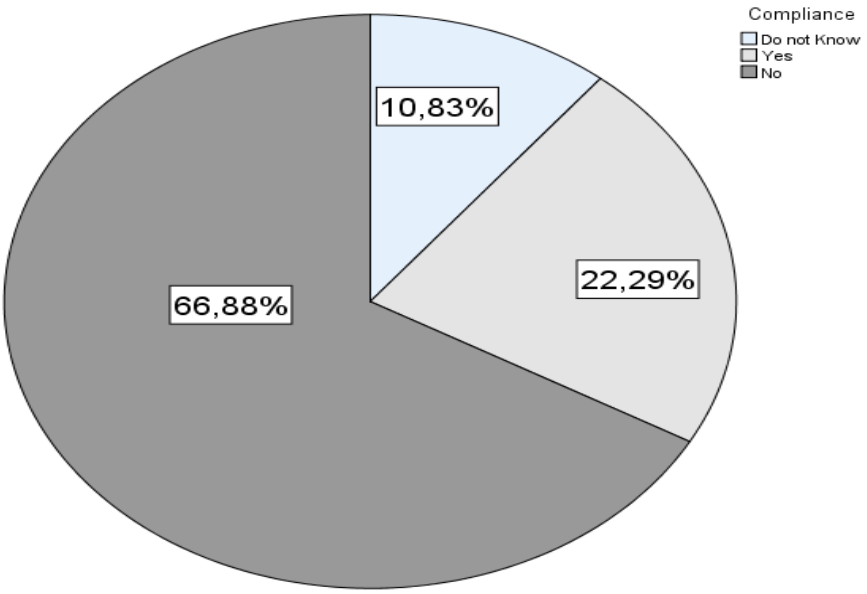

Figure 3: Pie chart for self-reported dietary compliance

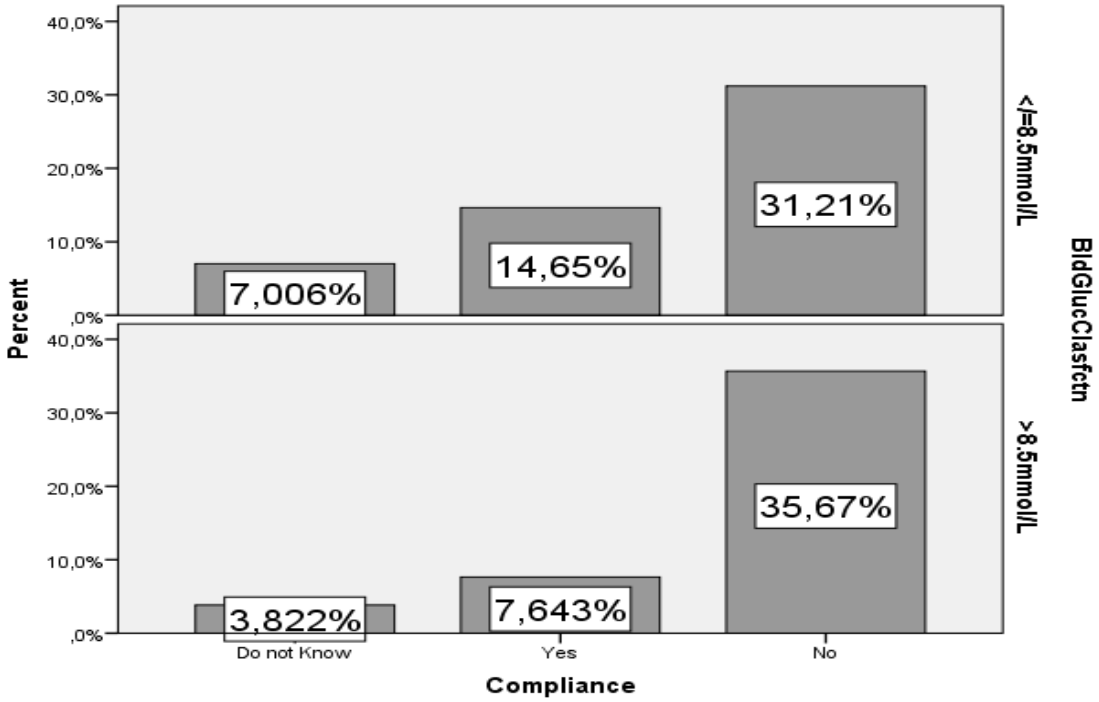

Figure 4: Self-reported dietary compliance versus glycemic control

APPENDIX 3: BUDGET

ACTIVITIES	QUANTITY	RATE (KSh.)	TOTAL (KSh.)
PROPOSAL WRITING			
Stationery			
Printing Papers	2 reams	500	1000
Flash Disk (32 GB)	1 piece	2500	2500
Printing and Binding			
Printing (8 copies)	40 pages per copy	400	3200
Binding (loosely)	8 copies	100	800
Subsistence			
Subsistence	10 days	500	5000
Literature Review			
Transport	5 days	0	0
Subsistence	5 days	500	2500
SUB-TOTAL			**15000**
DATA COLLECTION			
Printing Questionnaires	160 copies	80	12800
Printing ICF	160	20	3200
Subsistence	10 days	500	5000
Transport (local)	10 days	300	3000
SUB-TOTAL			**24000**
THESIS PREPARATION			
Typing and Printing (8 copies)	80 pages per copy	800	6400
Binding (loosely)	8 copies	100	800
Subsistence	7 days	500	3500
SUB-TOTAL			**10700**
CONTINGENCIES (10%)			**4970**
GRAND TOTAL			**54670**

Note: In August 2014 €0.0085 = KSh. 1(NSE, 2014)
Approximately €470

APPENDIX 4: QUESTIONNAIRE USED IN THE SURVEY

Please answer every question by filling in the blank(s), circling the correct answer, or ticking the correct answer.

Date _____

Section I- Personal Information

Gender: _____

Residence: _____

Q1. How old were you on your last birthday? (tick one box)

A. Less than 35

B. 35-44

C. 45-54

D. 55-64

E. 65 and older

Q2. What is the highest level of education attained? (tick one)

A. Primary

B. Secondary

C. College

D. University

E. Did not attend formal education

Q3. What is your estimated monthly income? (please tick one)

A. Kshs. 10,000 and below

B. Kshs. 10,000 to 20,000

C. Kshs. 20,000 to 50,000

D. Kshs. 50,000 to 80,000

E. Kshs. 80,000 to 100,000

F. Kshs. 100,000 and above

Q4. Does any member of your family (first relatives) been diagnosed with type-1 or type-2 diabetes? (tick one)

A. Yes

B. No

Section II – Resource Use

Q1. During the past 4 weeks, how many total visits to health care providers (doctors, nurse, practitioners, etc.) did you make? (fill in the blanks)

___visits in the past 4 weeks

Q2. During the past 12 months, how many total visits to health care providers did you make? (fill in the blanks)___visits in the past 12 months

Q3. When was your last visit with the following health care providers?

a. My last visit with a **dietitian** was: (tick one)

A. Within the last 12 months

B. 1-2 years ago

C. 2-3 years ago

D. More than 3 years ago

E. Never had a visit with a dietitian

b. My last visit with a **diabetes educator** was: (tick one)

A. 1-2 years ago

B. 2-3 years ago

C. More than 3 years ago

D. Never had a visit with a diabetes educator

Q4. When was the last time that you had the following blood tests?

a. My last **Hemoglobin A1c test** was: (tick one)

(This is also known as glycol-hemoglobin or glycosylated hemoglobin, a test that measures your average blood sugar level over the past couple of months)

A. 1-2 years ago

B. 2-3 years ago

C. More than 3 years ago

D. Never had a Hemoglobin A1c test

b. My last **Cholesterol blood test** was: (tick one)

A. 1-2 years ago

B. 2-3 years ago

C. More than 3 years ago

D. Never had a Cholestrol blood test

c. My last **Urine analysis** was: (tick one)

(Gave a urine sample to be tested by the health care provider, clinic, or laboratory)

A. 1-2 years ago

B. 2-3 years ago

C. More than 3 years ago

D. Never had a Urine analysis

Q5a. Do you check your own blood sugar? (tick one)

A. No

B. Yes

b. How many days a week do you test your blood sugar? (fill in the blank)

_____ (days / week)

Q6. During the past 12 months, were you a patient in a hospital overnight? (tick one)

A. No

B. Yes

Q6a. How many times in the past 12 months did you stay in a hospital overnight? (fill in the blank) _____times

Q6b. How many nights altogether during the past 12 months did you stay in a hospital? (fill in the blank) _____nights

Q7. Have you ever been hospitalized for diabetic ketoacidosis (DKA)? (tick one)

A. No

B. Yes

C. Don't Know

Section III– Medication Use

Q1. Do you now use insulin? (tick one)

A. No

B. Yes

Q1a. How many times during the day do you usually take your insulin? (tick one)

A. Once a day (Taken in the **Morning**)

B. Once a day (Taken in the **Evening**)

C. Twice a day

D. Three times a day

E. Four or more times a day

F. I use an infusion pump

Q1b. How long have you taken insulin? (fill in the blank) ____years

Q1c. Have you taken insulin for as long as you have had diabetes? (tick one)

A. No

B. Yes

Q2. In the past year, have **you** made changes in your insulin or pill dose on the basis of your home blood tests? (tick one)

A. No

B. Yes

C. Not using medications

D. Don't test

Q3. Do you change the timing/content of a meal on the basis of your home blood tests? (tick one)

A. No

B. Yes

C. Don't test

Q4. Are you currently taking medications for high cholesterol? (tick one)

A. No

B. Yes

C. Don't know

Section IV – Satisfaction

Q1. These questions ask about the diabetes care you have received recently. (tick one answer on each line)

1. Strongly Disagree **2. Disagree** **3. Not Sure**

4. Agree Strongly **5. Agree**

Q1a. I'm very satisfied with the **diabetes care** I receive. 1 2 3 4 5

Q1b. The **diabetes care** received could be better. 1 2 3 4 5

Q1c. The **diabetes care** I have received in the last few years is just about perfect. 1 2 3 4 5

Q1d. There are things about the **diabetes care** I receive that could be better. 1 2 3 4 5

Q2. Who currently provides your main diabetes health care? (tick only one)

A. Clinical Officers (C.O.)

B. Foot Care Specialist

C. Nurse Educator

D. Nutritionist

C. Other (please specify): _____

Section V – Background Information

Q1. Height? _____cms

Q2. Current weight? _____kg

Q3. BMI? _____

Q4. Waist Circumference? _____cms

Q5. Blood Glucose Levels? _____

Q6. In the last three months, have you been drinking alcoholic drinks at all (e.g. beer, wine, whiskey, gin, vodka or other hard liquor)?

A. No

B. Yes

Q6a. How many days in a week do you typically have something to drink? (tick one answer)

None 1 2 3 4 5 6 7

Q6b. On days that you drink, how many drinks do you typically have? (tick one answer)

1 2 3 4 5 6 7 8 9 10 11 12 13 14 or more

Q7. Do you now smoke cigarettes? (tick one)

A. No

B. Yes

Q7a. How many cigarettes per day do you smoke? ____ packs per day

Section VI – Reasons patient came to the clinic

Q1. How did you first hear about this clinic? (tick one only)

A. Letter from the _____

B. My health care provider

C. Newspaper

D. My diabetes educator

E. A public health nurse

F. Support group/friends/other patients

G. Other, please list: _____

Q2. What was the most important reason you came to the clinic? (tick one only)

A. To see if diabetes was affecting my health

B. My health care provider told me to come

C. My diabetes educator told me to come

D. It was a free clinic

E. Other, please list: _____

Q3. What are the three most difficult problems you face in caring for your diabetes? (Try to be as specific as possible - if you can't think of three problems, list as many as you can think of.)

1._____

2._____

3._____

Section VII - Detailed Diet / Nutrition Counseling

Q1. Did you ever see a dietitian to learn about a diabetic meal plan or diet? (tick one)

A. No

B. Yes

Q1a. About how many times have you seen a dietitian?

A.1-2 times

B. 3-5 times

C. More than 5 times

Q1b. Do you have a regularly scheduled visit(s)?

A. Yes

B. No

____ times

Q1c. When was the last time you saw a dietitian to learn about or review your diabetes meal plan or diet? (please enter the year)

_____

Q1c. Was there a charge for seeing the dietitian the last time? (tick one)

A. No, there was not a charge

B. Yes, there was a charge

C. Not sure if there was not a charge

Q1c1. If Yes, who paid for the charge for seeing the dietitian? (tick one box)

A. I did

B. Insurance company

C. Wasn't paid

D. Not sure

Q2. If you have never seen a dietitian, why not? (check one box)

Costs too much

A. Not sent by my health care provider

B. Did not feel it was important

C. Didn't know I was supposed to

D. My health care provider tells me about my diet

E. Other, please list: _____

Section VIII - 24-Hour Dietary Recall

Q1. Which day of the week does this record? (tick one)

___Mon ___Tues ___Wednes ___Thurs ___Fri ___Sat ___Sun

Q2. Please give a record of all food and drink for the complete day, including snacks and the time period. Use the following as an example.

Breakfast (between 6am to 9 am): 2 cups of tea with milk + 2 slices of bread/ maandazi/ nduma; 2 mugs of porridge; food left overnight + 1 cup water

Mid-morning snack (between 10am to11am): 1 cup tea with sugar + 1 andazi/ piece of sweet potato/ yam/ nduma

Lunch (between 1pm to 2 pm): One plate of rice with beans stew + 1 cup water

Afternoon snack (at 4pm): 1 cup tea

Evening (between 7pm to 11pm): ugali + sukumawiki + beef.

……

……

……

Q2a. Does this record represent a typical day? (tick one)

A. Yes

B. No

Q2b. For those receiving nutrition counselling, does this record comply with recommendations given? (tick one)

A. Yes

B. No

Q3. Do you currently take vitamin supplements?

A. No

B. Yes

Q3a. If Yes, Please list all supplements:…….

Q4. Do you currently take herbal medications?

A. No

B. Yes

Q4a. If Yes, Please list all herbal medications:…….

THANK YOU!!!

APPENDIX 5: INFORMED CONSENT FORM

INFORMED CONSENT FORM FOR COMPARISON OF DISEASE MANAGEMENT PRACTICES AND DIETARY PRACTICES IN DIABETES' PATIENT WITH GOOD AND POOR GLYCEMIC CONTROL.

This Informed Consent Form is for men and women who attend the Kenyatta National Hospital Diabetes Clinic, and who I am inviting to participate this research focusing on diabetes mellitus Type II patients in Kenya.

Name of Principal Investigator: LINET NKIROTE MUTWIRI
Name of Institution: UNIVERSITY OF GENT

I am a student at the University of Gent, Belgium. I am carrying out a research on Diabetes Mellitus type II, which is common in this country. I am going to give you information and invite you to be part of this research. You can decide whether or not you will participate in the research. Before you decide, you can talk to anyone you feel comfortable with about the research.

There may be some words that you do not understand. Please ask me to stop as I go through the information and I will take time to explain. If you have questions, you can ask them of me.

Purpose of the research

Diabetes mellitus Type II is one of the most common lifestyle diseases in Kenya. Management of the disease encompasses patients' behavior and lifestyle modification. This can be greatly enhanced by the adhering to principles channeled through provision of education, care and empowerment in diabetes clinics at health centers, diet adjustments and engaging in exercise. It helps patients' general improvement in a patient's ability to cope with their disease, monitor their own blood glucose trends and most important improves the chance of achieving optimal glycemic levels. The reason I am doing this research is to find out the differences in diabetes patients having a good glycemic control and those having a poor control in relation to the above named factors among diabetes patients attending the diabetes outpatient clinic at Kenyatta National Hospital.

Type of Research Intervention

This research will involve collection of dietary data and clinical measurements. A validated questionnaire will be used to collect the patients with diabetes' personal information and dietary data. Personal information to be collected will be on age, residence town, estimated monthly family incomes, previous and current nutrition habits, historical data on personal health, family health and social behavior. Dietary information to be collected is diet intake composition, dietary adequacy, compliance with diet prescription (for those receiving nutrition counselling), dietary diversity, meal frequency, frequency of intake of salty food, and high fat/high cholesterol food use.
Measurements to be taken are height, weight and waist circumference

Blood glucose levels will be obtained from clinical measurements done by the hospital staff on the patients with diabetes.

Participant selection

I am inviting all adults with diabetes mellitus Type II who attend the Kenyatta National Hospital Diabetes Clinic to participate in the research. Do you know why I am asking you to take part in this study? Do you know what the study is about?

Voluntary Participation

Your participation in this research is entirely voluntary. It is your choice whether to participate or not. Whether you choose to participate or not, all the services you receive at this clinic will continue and nothing will change. You may change your mind later and stop participating even if you agreed earlier. Do you have any questions?

Duration

The questionnaire seeks information on dietary intake, satisfaction levels of diabetes care received and disease management practices.

The research takes place over a few days but information will be collected from you only once. The self-administered questionnaire takes about 10 minutes to be completely filled in. You will not be provided any incentive to take part in the research.

Risks

I am asking you to share some personal information. The topics though are not necessarily uncomfortable to discuss. You do not have to answer any question or take part in the survey if you don't wish to do so, and that is also fine. You do not have to give any reason for not responding to any question, or for refusing to take part in the interview.

Benefits

There will be no direct benefit to you, but your participation is likely to help us find out more about how to prevent and manage diabetes better among diabetes patients.

Confidentiality

The study does not need your name and the questionnaire will be numbered instead. No information shared by you will be disclosed or shared with or given to anyone except the study promoters. The information collected from this research will be kept private.
None of the information you provide will be attributed to you by name. The findings will be analysed and used to generate a summary of the results and a general report that will be submitted to Kenyatta National Hospital for audit purposes. The study results and discussion will be published so that other interested people may learn from the research.

Right to Refuse or Withdraw

You do not have to take part in this research if you do not wish to do so, and choosing to participate will not affect the service received from the clinic in any way. You may stop participating at any time that you wish.

Who to Contact

If you have any questions, you can ask them now or later. If you wish to ask questions later, you may contact:

Linet Nkirote Mutwiri, Mobile: +254716333046, E-mail: tenilynn@gmail.com

This proposal has been reviewed and approved by the Ethical Research Committee of the Gent University, Belgium.

The KNH/UON ERC committee whose task it is to make sure that research participants are protected from harm has also reviewed the proposal. If you wish to find about more about the KNH/UON ERC, contact can be made through the following: Telephone- 2726300 ext 44102; E-mail address- uonknh_erc@uonbi.ac.ke; or visit the website is www.uonbi.ac.ke.

PART II: Certificate of Consent

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research.

Signature of Participant _____

Date _____

Statement by the researcher/person taking consent

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands the scope of the study. I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

Name and Signature of Researcher/person taking the consent _____

Date _____